Effective Health Care Program

Future Research Needs Paper
Number 15

Vaginal Birth After Cesarean: Developing and Prioritizing a Future Research Agenda

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Vaginal Birth After Cesarean: Developing and Prioritizing a Future Research Agenda

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The information in this report is intended to help health care researchers and funders of research make well-informed decisions in designing and funding research and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of scientific judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical research and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances.

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None of the investigators has any affiliations or financial involvement that conflicts with the material presented in this report.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

An important part of evidence reports is to not only synthesize the evidence, but also to identify the gaps in evidence that limited the ability to answer the systematic review questions. AHRQ supports EPCs to work with various stakeholders to identify and prioritize the future research that is needed by decisionmakers. This information is provided for researchers and funders of research in these Future Research Needs papers. These papers are made available for public comment and use and may be revised.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality. The evidence reports undergo public comment prior to their release as a final report.

We welcome comments on this Future Research Needs document. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Vaginal Birth After Cesarean: Developing and Prioritizing a Future Research Agenda

Structured Abstract

Objectives: The objective of this Future Research Needs project is to develop a future research agenda in the area of vaginal birth after cesarean (VBAC) that builds on the research gaps identified in the 2010 evidence review conducted for the National Institutes of Health (NIH) Consensus Development Conference.

Data Sources: In phase 1, stakeholders participated in semistructured interviews to identify and describe evidence gaps and future research needs. In phase 2, stakeholders participated in a modified Delphi process to rank the top 10 research priorities. Ongoing studies and recently completed research between March 2010 and August 2011 were identified by searching Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Cochrane Database of Reviews of Effects (DARE), Ovid MEDLINE®, Scopus, the Annals of Internal Medicine Web site, Google Scholar, clinical trial registries, grant databases, and individual funders' Web sites.

Results: Sixteen of the 30 stakeholders invited to participate in the semistructured interviews agreed. Overall, 6 of the 6 legal/liability or hospital administrators (100 percent), 2 of the 6 patient/consumer advocates (33 percent), 5 of the 13 clinicians (30 percent), 1 of the 2 researchers (50 percent), and 2 of the 3 research funders (66 percent) were interviewed. We invited 11 stakeholders to participate in the phase 2 Delphi process. In compliance with Federal guidelines, only nine of the stakeholders were not Federal employees. All stakeholders invited to participate in the Delphi prioritization process completed the first questionnaire, and 10 of the 11 completed the second questionnaire (81 percent). A list of the top 10 research priorities was developed.

Conclusions: The top 10 future research needs as prioritized by stakeholders fall into three overarching categories: health systems and contextual issues (category A), standardized measurement and collection of data on maternal and infant outcomes (category B), and understanding how patients perceive risk and how best to communicate risk of mode of delivery after prior cesarean (category C). Within category A, stakeholders highlighted the need for research on institutional and systems-level barriers and facilitators to providing and delivering safe trials of labor after cesarean, including how the "immediately available" requirement is understood and implemented and concerns about legal liability. Within category B, stakeholders emphasized measurement of both short- and long-term outcomes and the importance of agreement on clear and precise definitions and methods of ascertainment both within and across hospitals. With regard to category C, stakeholders prioritized research about how patients perceive the risks of trial of labor (TOL) compared with repeat cesarean delivery, how best to frame and communicate the risks of each option, and the most effective way to present information so that women can make an informed choice that incorporates their preferences. Overall, stakeholders felt that defining what constitutes a "safe" TOL after cesarean and safe

birth in general, at the level of the individual, the provider, and the institution or setting of care was important across all top priority research needs.

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Executive Summary

Background

The rate of cesarean delivery in the United States increased dramatically over the past two decades, from 20.7 percent in 1996 to 32.8 percent in 2010.[1] Part of the reason for the increase is a decline in the rate of vaginal birth after cesarean (VBAC).[2] Although the dictum "once a cesarean, always a cesarean" guided clinical practice for a good part of the 20th century, a 1980 National Institutes of Health (NIH) Consensus Development Conference Panel recognized trial of labor (TOL) after prior cesarean as a viable option for certain low-risk women.[3] An increase in VBAC ensued; by 1996, more than 28 percent of women with a prior cesarean delivered vaginally.[2] However, a number of medical and nonmedical factors, including reports in the 1990s of an increased risk of maternal complications with TOL compared with elective repeat cesarean, pushed the pendulum in the opposite direction.[3,4] The percentage of women with a previous cesarean delivering vaginally fell from a peak of 28 percent in 1996 to 8.5 percent in 2007.[2]

In 2010, NIH again convened a Consensus Development Conference Panel to evaluate the growing body of evidence on the clinical risks and benefits of TOL after cesarean. In preparation for the 2010 conference, the Agency for Healthcare Research and Quality (AHRQ) commissioned the Oregon Evidence-based Practice Center (EPC) to conduct a review of the evidence on a number of emerging issues related to VBAC,[3] which was released as AHRQ Evidence Report/Technology Assessment No. 191.[5] The evidence review addressed the following six Key Questions.

1. What are the rates and patterns of utilization of trial of labor after prior cesarean, vaginal birth after cesarean, and repeat cesarean delivery in the United States?
2. What are the nonmedical factors (e.g., provider type, hospital type) that influence the patterns and utilization of trial of labor after prior cesarean?
3. Among women who attempt a trial of labor after prior cesarean, what are the vaginal delivery rate and the factors that influence it?
4. What are the short- and long-term benefits and harms to the mother of attempting trial of labor after prior cesarean compared with elective repeat cesarean delivery, and what factors influence benefits and harms?
5. What are the short- and long-term benefits and harms to the baby of maternal attempt at trial of labor after prior cesarean compared with elective repeat cesarean delivery, and what factors influence benefits and harms?
6. What are the critical gaps in the evidence for decisionmaking, and what are priority investigations needed to address these gaps?

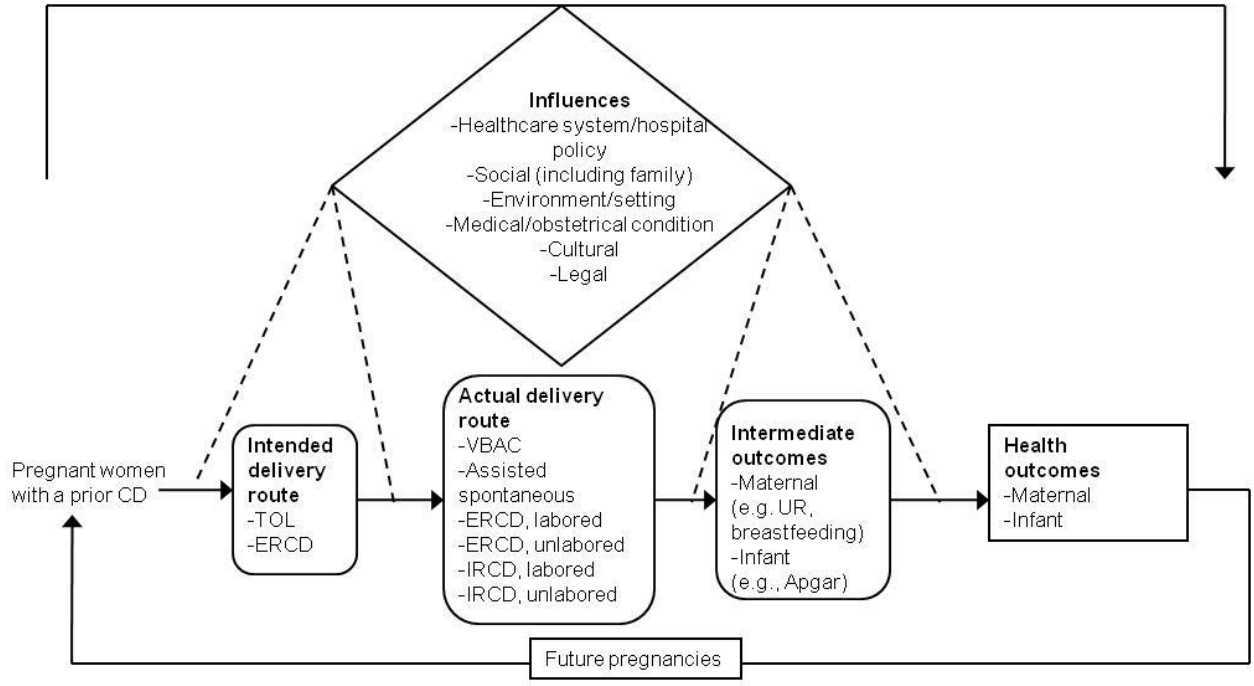
Figure A presents the analytic framework incorporating information on the population, interventions, comparators, and outcomes (PICO) that pertain to all six Key Questions.

While the evidence review addressed all six questions, Key Questions 3–6 were the main focus for presentation at the NIH Conference. Therefore, prior to the conference, external peer reviewers were asked to comment and prioritize research gaps for Key Questions 3–6. The aim

of this Future Research Needs project is to identify and prioritize future research needs addressed in the entire evidence review.

Both the systematic review and the Conference revealed that VBAC rates continued to decline despite evidence supporting VBAC as a safe option. This suggests that the contextual and nonmedical factors in the first two questions are likely major drivers of health care delivery. The review found a paucity of research in these domains (Key Questions 1–2), emphasizing the importance of indepth investigation and development of potential research questions and research designs with key stakeholders. This report therefore generates future research topics for Key Questions 1–2 in order to prioritize across all six Key Questions of the evidence review.

Figure A. Original analytic framework from evidence review



CD = cesarean delivery; ERCD = elective repeat cesarean delivery; IRCD = indicated repeat cesarean delivery; TOL = trial of labor; UR = uterine rupture; VBAC = vaginal birth after cesarean

Methods

A sample of stakeholders with interests in VBAC research—including clinicians, consumer advocates, research funders, researchers, legal/liability representatives, and hospital administrators—were invited to participate in prioritizing a future research agenda for VBAC. Recruitment was conducted from May to June 2011.

In phase 1 we conducted indepth interviews with stakeholders to understand and refine evidence gaps, with a particular emphasis on identifying potential nonmedical and contextual research questions. In phase 2, stakeholders completed two rounds of a Delphi process to identify and rank the top 10 research priorities. The questionnaires were constructed from information gaps identified in the 2010 evidence review, through informational interviews with the lead investigator of the evidence review, and through interviews with stakeholders. Both structured questions and open-ended narrative responses were used to identify high-priority research topics, and those topics were searched in the recent VBAC literature.

For each of the structured questions, stakeholders were asked to indicate whether the topic was low, medium, or high priority for future research and to provide narrative text to indicate additional detail on the types of research they recommended. At the end of the questionnaire, we provided a list of all topics and asked respondents to choose the 10 highest priority areas. In order to come to a more definitive consensus on the top 10 research priorities, in a second round stakeholders were asked to rank order the top 10 research priorities from a list of the 15 highest priority areas identified in round 1. The second prioritization questionnaire was sent electronically to participants on July 26, 2011, and they were asked to complete and return it by August 1, 2011.

Ongoing studies and recently completed research between March 2010 and August 2011 were identified by searching Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Cochrane Database of Reviews of Effects (DARE), Ovid MEDLINE®, Scopus, the Annals of Internal Medicine Web site, Google Scholar, clinical trial registries, grant databases, and individual funders' Web sites.

Results

We invited 30 stakeholders to participate in the phase I semistructured interviews, and of those 16 agreed to participate. Overall, we conducted individual or group interviews with 6 of the 6 legal/liability or hospital administrator stakeholders (100 percent), 2 of the 6 patient/consumer advocates (33 percent), 5 of the 13 clinicians (30 percent), 1 of the 2 researchers (50 percent), and 2 of the 3 research funders (66 percent). We categorized the identified research areas into four overarching themes: health systems (9 questions); risk, attitudes, and decisionmaking (7 questions); shared decisionmaking and informed consent (5 questions), and maternal and infant outcomes (12 questions). These four categories included the gaps identified during the 2010 evidence review as well as those identified during the semistructured interviews in phase 1.

We invited 11 stakeholders to participate in the phase 2 Delphi process. In compliance with Federal guidelines, only nine of the stakeholders were not Federal employees. All 11 stakeholders invited to participate in phase 2 completed the first questionnaire, and 10 of the 11 completed the second questionnaire (81 percent). Of the stakeholders who participated in phase 2 one was a hospital administrator, two were patient/consumer advocates, five were clinicians, one was a researcher, and two were research funders. A list of the top 10 research priorities was developed.

The top 10 research questions arising from the phase 2 prioritization are listed in Table A. The research priorities identified cluster into three overarching categories: health systems and contextual issues (category A), standardized measurement and collection of data on maternal and infant outcomes (category B), and understanding how patients perceive risk and how best to communicate risk of mode of delivery after prior cesarean (category C). In synthesizing the results, it is helpful to discuss each topic in the context of these categories.

Table A. Phase 2, Delphi round 2: Top 10 VBAC future research priorities

Priority	Final Rank	Weighted Score[a]	Category of Research
Studies to test clinical, institutional, or policy interventions to increase access to "safe" TOL	**1**	72	A
Research on barriers to providing safe TOL, including factors that limit hospitals' ability to meet the "immediately available" requirement (i.e., availability of anesthesiologists, obstetric providers, and other resources)	**2**	51	A
Studies comparing outcomes for mother and infant in settings where physicians are "immediately available" vs. settings where physicians are "readily available"	**3**	46	A
Studies to understand best-practice models based on institutions that are currently offering safe TOL	**4**	41	A
Development of standardized measures for short- and long-term maternal and infant outcomes	**5**	41	B
Surveillance to determine long-term clinical outcomes of TOL vs. ERCD	**6**	38	B
Research on how patients understand risk, how they respond to different ways of framing risk, and how best to communicate risks of TOL vs. ERCD	**7**	37	C
Clinical and policy-relevant studies to address the threat of legal liability on practice patterns regarding TOL vs. ERCD	**8**	34	A
Development/utilization of a reliable model or tool to predict the probability of successful VBAC for individual women and/or a tool to predict probability of successful VBAC in general	**9**	32	B
Studies to refine, validate, and implement informed-consent templates that are informative, reliable, and able to be well documented	**10**	26	C

ERCD = elective repeat cesarean delivery; TOL = trial of labor; VBAC = vaginal birth after cesarean. Categories of research: A = health systems and contextual issues; B = standardized measurement and collection of data on maternal and infant outcomes; C = understanding how patients perceive risk and how best to communicate risk of mode of delivery after prior cesarean.
[a] Weighted scores correspond to the prioritized ranking in the second round of phase 2.

Within the category of contextual or health systems factors (A), stakeholders felt it was important to study institutional and systems-level barriers and facilitators to providing and delivering safe trials of labor after cesarean, including how the "immediately available" requirement is understood and implemented, and concerns about legal liability. (The "immediately available" phrase is from the American Congress of Obstetricians and Gynecologists [ACOG] guideline, which states that "because of the risks associated with TOL after cesarean and that uterine rupture and other complications may be unpredictable, the College recommends that TOL after cesarean be undertaken in facilities with staff immediately available to provide emergency care".[6]) In the words of one of our stakeholders, "The epidemiology of VBAC at this point is well known…it couldn't be more consistent….We don't need any more [epidemiological] studies….We've got enough…so I think at this point it's about health care services...and outcomes research and trying to figure out how services…can be effectively disseminated to the community, be made available to women, and made available in such a way that women are actually receiving the health care that they desire."

Within the category of standardized measurement and collection of data on maternal and infant outcomes (B), stakeholders emphasized the importance of agreement on clear and precise definitions and methods of ascertainment both within and across hospitals. In addition to

measures of both short- and long-term clinical outcomes, stakeholders highlighted the need for measures of psychosocial factors such as post partum depression, quality of life, breastfeeding initiation, and maternal-infant bonding. Stakeholders also prioritized further data collection at the hospital level in order to develop a more comprehensive understanding of the impact of institutional structure and management on maternal and infant outcomes.

With regard to the third category, understanding how patients perceive risk and how best to communicate risk of mode of delivery after prior cesarean (C), stakeholders expressed uncertainty about how patients perceive the risks of TOL compared with elective repeat cesarean delivery (ERCD), how best to frame and communicate the risks of TOL compared with ERCD, and the most effective way to present information so that women can make an informed choice that incorporates their preferences. This was felt to be particularly important given the 2010 ACOG guidelines, which state that "after counseling, the ultimate decision to undergo TOL after cesarean or a repeat cesarean delivery should be made by the patient in consultation with her health care provider."[6]

Overall, stakeholders felt that defining what constitutes a "safe" TOL after cesarean, and a safe birth in general, at the level of the individual, the provider, and the institution or setting of care was important across all top priority research needs. As summed up by one of our stakeholders: "An important potential dilemma is defining what constitutes 'safe' TOL, in whose judgment is TOL 'safe' and where the 'immediately available' standard fits in that definition or if it even is an appropriate factor in the definition. Once safe is defined, find best practices [for] achieving it and test them in other settings."

Discussion

Half of the top 10 priorities for future research on VBAC fall in the category of health systems or contextual issues, a nascent field of research. As indicated in the evidence review, the ability to conduct large-scale studies in this area relies on the development of a standard terminology and documentation of process measures that accurately reflect the conduct of labor and delivery across a range of settings. Although childbirth is the leading reason for hospital admission in the United States, obstetric data systems both within and across hospitals "remain rudimentary and lack standardization."[7] While interest in measuring the quality of obstetric care is growing, to date there is no clear consensus as to what quality measures are most important to inform clinical decisionmaking and improve obstetric practices. Interestingly, even for the areas with more robust literature, such as maternal and infant health outcomes associated with TOL compared with ERCD, the development of standard terminology is a recognized deficiency that has yet to be fully addressed. The move from paper charts to the increasingly widespread use of electronic medical records provides a valuable opportunity to document and collect information on quality and safety both within and across hospitals, facilitating the development of best practices that can be replicated in a variety of settings.

Our research methodology has some limitations that deserve discussion. First, although the phase 2 Delphi questionnaire included a range of issues beyond health systems, the initial focus on questions about contextual and health systems factors during the semistructured interviews in phase 1 could have primed the respondents to rank these items higher during the phase 2 prioritization. Second, the small sample size of our stakeholder panel limits the generalizability of our findings. Finally, although every attempt was made to engage a balanced group of stakeholders, the group of clinicians was slightly larger than the other stakeholder groups in order to include the perspectives of physicians, midwives, and nurse practitioners.

Conclusion

The top 10 future research needs as prioritized by stakeholders fall into three overarching categories: health systems and contextual issues (category A), standardized measurement and collection of data on maternal and infant outcomes (category B), and understanding and communicating risk of mode of delivery after prior cesarean (category C). Within category A, stakeholders felt it was important to study institutional and systems-level barriers and facilitators to providing and delivering safe trials of labor after cesarean, including how the "immediately available" requirement is understood and implemented, and concerns about legal liability. Within category B, stakeholders prioritized standardized measurement and collection of data on short- and long-term maternal and infant outcomes and emphasized the importance of agreement on clear and precise definitions and methods of ascertainment both within and across hospitals. With regard to category C, stakeholders prioritized research about how patients perceive the risks of TOL compared with ERCD, how best to frame and communicate the risks of each option, and the most effective way to present information so that women can make an informed choice that incorporates their preferences. Overall, stakeholders felt that defining what constitutes a "safe" TOL after cesarean, and safe birth in general, at the level of the individual, the provider, and the institution or setting of care was important across all top priority research needs.

References

1. Hamilton BE, Martin JA, Ventura SJ. Births: preliminary data for 2010. Natl Vital Stat Rep. 2011;60(2). www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr. Accessed January 9, 2012.
2. Martin JA, Hamilton BE, Sutton PD, et al. Births: final data for 2007. Natl Vital Stat Rep. 2010;58(24). www.cdc.gov/nchs/data/nvsr/nvsr58/nvsr.
3. National Institutes of Health Consensus Development Conference Statement. Vaginal Birth After Cesarean: New Insights, March 8-10, 2010. Obstet Gynecol. 2010 Jun;115(6):1279-95. PMID: 20502301.
4. McMahon M, Luther E, Bowes W, et al. Comparison of a trial of labor with an elective second cesarean section. N Engl J Med. 1996;335(10):689-95. PMID: 8703167.
5. Guise J-M, Eden K, Emeis C, et al. Vaginal Birth After Cesarean: New Insights. Evidence Report/Technology Assessment No. 191. (Prepared by the Oregon Health & Science University Evidence-based Practice Center under Contract No. 290-2007-10057-I.) AHRQ Publication No. 10-E003. Rockville, MD: Agency for Healthcare Research and Quality. March 2010.
6. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 115: Vaginal birth after previous cesarean delivery. Obstet Gynecol. 2010 Aug;116(2 pt 1):450-63.
7. MacDorman M, Declercq E, Menacker F. Recent trends and patterns in cesarean and vaginal birth after cesarean (VBAC) deliveries in the United States. Clin Perinatol. 2011;38(2):179-92. PMID: 21645788.

Introduction

The rate of cesarean delivery in the United States increased dramatically over the past 2 decades, from 20.7 percent in 1996 to 32.9 percent in 2010.[1] Part of the reason for the increase is a decline in the rate of vaginal birth after cesarean (VBAC).[2] Although the dictum "once a cesarean, always a cesarean" guided clinical practice for a good part of the 20th century, a 1980 National Institutes of Health (NIH) Consensus Development Conference Panel recognized trial of labor (TOL) after prior cesarean as a viable option for certain low-risk women.[3] An increase in VBAC ensued; by 1996, more than 28 percent of women with a prior cesarean delivered vaginally.[2] However, a number of medical and nonmedical factors, including reports in the 1990s of an increased risk of maternal complications with TOL compared with elective repeat cesarean, pushed the pendulum in the opposite direction.[3,4] The percentage of women with a previous cesarean delivering vaginally fell from a peak of 28 percent in 1996 to 8.5 percent in 2007.[2]

In 2010, the NIH again convened a Consensus Development Conference Panel to evaluate the growing body of evidence on the clinical risks and benefits of TOL after cesarean.[3] In preparation for the 2010 conference the Agency for Healthcare Research and Quality (AHRQ) commissioned the Oregon Evidence-based Practice Center (EPC) to conduct a review of the evidence on a number of emerging issues related to VBAC,[3] which was released as AHRQ Evidence Report/Technology Assessment Number 191.[5] The evidence review addressed the following six Key Questions.

1. What are the rates and patterns of utilization of trial of labor after prior cesarean, vaginal birth after cesarean, and repeat cesarean delivery in the United States?
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3. Among women who attempt a trial of labor after prior cesarean, what are the vaginal delivery rate and the factors that influence it?
4. What are the short- and long-term benefits and harms to the mother of attempting trial of labor after prior cesarean compared with elective repeat cesarean delivery, and what factors influence benefits and harms?
5. What are the short- and long-term benefits and harms to the baby of maternal attempt at trial of labor after prior cesarean compared with elective repeat cesarean delivery, and what factors influence benefits and harms?
6. What are the critical gaps in the evidence for decisionmaking, and what are priority investigations needed to address these gaps?

Figure 1 presents the analytic framework incorporating information on the population, interventions, comparators, and outcomes (PICO) that pertain to all six review questions.

While the evidence review addressed all six questions, Key Questions 3-6 were the main focus for presentation at the NIH Conference. One of the major findings of the 2010 evidence review was that the best evidence suggests VBAC is a reasonable and safe choice for the majority of women with prior cesarean. The authors report that maternal and infant mortality for women with prior cesarean is not significantly elevated when compared with overall national rates of mortality in childbirth. Further, the majority of women who undergo TOL after prior cesarean will have a successful VBAC, and they and their infants will be healthy.[5] However, the juxtaposition of maternal and fetal risks makes the decision to have a VBAC particularly

complicated. The 2010 evidence review reported that maternal mortality is significantly higher for elective repeat cesarean delivery (ERCD)[a] than for TOL after cesarean (13.4 vs. 3.8 deaths per 100,000).[5] On the other hand, although very rare, catastrophic fetal outcomes are more common for TOL after cesarean, with an overall perinatal death rate of 1.3 per 1,000 for TOL after cesarean compared with 0.5 per 1,000 for ERCD.[5] To date, sophisticated statistical models for TOL after cesarean have not been able to predict who will do well and who will be harmed.

Both the systematic review and the NIH Conference revealed that VBAC rates continue to decline despite evidence supporting this as a safe option. This suggests that contextual and nonmedical factors are major drivers of health care delivery. The review found a paucity of research in these domains (Key Questions 1–2), emphasizing the importance of indepth investigation and development of potential research questions and research designs with key stakeholders.

Evidence Gaps

Prior to the NIH Conference, external peer reviewers—including representatives of Federal agencies (U.S. Food and Drug Administration, Centers for Disease Control and Prevention, and NIH), maternity and pediatric clinicians, advocacy groups, payers, policymakers, content experts, and researchers—were asked to comment and prioritize research gaps for Key Questions 3-6. Peer reviewers were asked to rate topics as low, medium, or high priority for future research, and to provide additional clarification on their positions. Those areas that were rated as highest priority (with at least 50 percent of experts rating the domain as high) are summarized below.

Evidence Gaps—Priorities From the 2010 Evidence Review

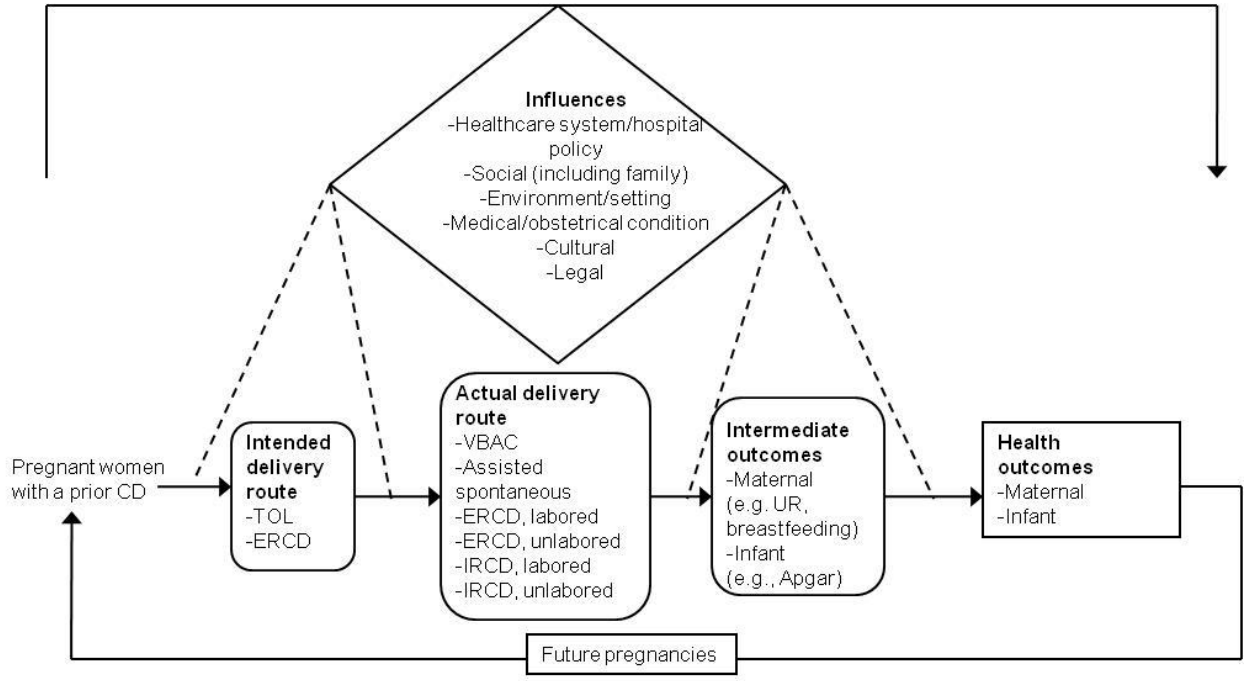
- Population-level research on patterns of utilization and maternal/infant outcomes of VBAC, TOL with emergent cesarean, and ERCD, stratified by race/ethnicity and socioeconomic status.
- Surveillance to determine important long-term clinical outcomes of VBAC, emergent cesarean, or ERCD.
- Investigation of whether antepartum or intrapartum management strategies—such as induction of labor—influence maternal/infant outcomes and rates of VBAC, TOL with emergent cesarean, and ERCD.
- Effect of cumulative dose and regimen of induction agent (PGE2, oxytocin, etc.) on maternal and infant harms.
- Imaging as a modality to predict uterine rupture or other outcomes.
- Studies that correlate benefits and harms of VBAC, TOL with emergent cesarean, and ERCD with short- and long-term health system costs.
- Clear and precise definitions and measurement of maternal and infant health outcomes associated with the different delivery methods (e.g., VBAC, TOL with emergent cesarean, or ECRD).
- Development of standardized measures for short-and long-term maternal and infant outcomes with VBAC, TOL with emergent cesarean, and ERCD.

[a] Elective repeat cesarean delivery refers to the option of planned repeat cesarean delivery as opposed to attempting a trial of labor. The term elective is meant to distinguish from medically indicated cesarean delivery, which is offered when the health of the mother or infant is at risk. It is important to recognize that elective does not always mean that a woman herself is "choosing" to have a repeat cesarean. In many cases access to TOL after cesarean is limited and many providers are unable to offer this option.

    - Short term: infection, surgical injury
    - Long term: pelvic floor disorders, quality of life
- Studies to compare the impact of VBAC, TOL with emergent cesarean, and ERCD on breastfeeding initiation and continuation.

The 2010 evidence review and the NIH Consensus Development Conference Statement highlighted several nonmedical factors that play an important role in decisionmaking about and access to TOL after cesarean—including professional liability concerns, professional and institutional policies, patient insurance type, and provider and patient attitudes.[6,7] As presented at the NIH Conference, many hospitals have chosen either officially or unofficially to ban women who had a previous cesarean from attempting a TOL in subsequent births.[7,8] Despite the influence of these factors on decisionmaking and access to TOL, both the 2010 evidence review and the NIH Consensus Statement concluded that data to judge the relative impact and interaction of these factors are lacking and that additional research is warranted. Given few examples of obstetric health care system delivery and contextual research, engaging a broad array of stakeholders to understand the outcomes and design that would be most informative to drive change is important. Accordingly, this Future Research Needs project consists of two phases. In phase 1, we engage a panel of stakeholders to identify the most important research gaps, with a particular focus on potential research questions relating to contextual and nonmedical factors that influence practice patterns. In phase 2, we ask stakeholders to prioritize across all of the six evidence review questions to provide a full spectrum of future research needs.

Figure 1. Original analytic framework from evidence review



CD = cesarean delivery; ERCD = elective repeat cesarean delivery; IRCD = indicated repeat cesarean delivery; TOL = trial of labor; UR = uterine rupture; VBAC = vaginal birth after cesarean

Methods

This project proceeded in two phases. In phase 1 we conducted in-depth interviews with stakeholders to understand and refine evidence gaps with a particular emphasis on identifying potential nonmedical and contextual research questions. In phase 2 we engaged a panel of stakeholders in two rounds of modified Delphi in order to arrive at consensus on the overall top 10 priority areas for future research. The proposal for this project was reviewed by the Oregon Health & Science University Institutional Review Board which determined that it did not meet the definition of human subject research, per 45 CFR 46.102(f) (IRB #: IRB00007178). Figure 2 describes the phases of the study design.

Identification and Recruitment of Stakeholders

A list of clinicians, consumer advocates, research funders, researchers, legal/liability representatives, and hospital administrators with interests in vaginal birth after cesarean (VBAC) research was generated a priori by the research team. A key concern in recruitment of participants was obtaining representation of relevant stakeholder groups.

Recruitment was conducted from May to June 2011. Overall, during phase 1 of our study, we contacted 30 organizations and individuals, including six patient/consumer advocates, 13 frontline clinicians, six legal liability/hospital administrators, three research funders, and two researchers. Consumer advocates were recruited from private and public organizations specific to women's reproductive health. Hospital administrators and representatives of the legal/liability perspective were recruited from professional medical societies, medical liability groups, and Federal organizations. Thirteen clinicians involved in obstetrics and gynecology practicing in both rural and private practice settings and two involved in university research were invited to participate. Additionally, two research funders from Federal funding agencies were invited to participate.

Stakeholders were emailed invitation letters (See Appendixes A and B) with followup and reminder phone calls as needed. The email invitation included an overview of our project, what their participation would entail, and contact information should they have any questions. Once they indicated willingness to participate, a member of our research team responded with potential times for an interview. Stakeholders were informed that phase 2 of the project would involve participation in an initial 30-minute prioritization questionnaire, followed by one to two additional rounds of prioritization (less than 10 minutes each) to rank the selected research areas.

Interviews were voluntary and participants were free to decline to answer any question or to address additional issues. We invited 11 stakeholders to participate in the phase 2 Delphi process. In compliance with Federal guidelines, only 9 of the stakeholders were not Federal employees. Individuals unable to participate in the online questionnaires were faxed a printed version of the questionnaire to complete. Participants were contacted by e-mail reminder up to three times. An overview of the study design is presented in Figure 2.

Disclosure and Evaluation of Conflicts of Interest

All participating stakeholders received the "EPC Conflict of Interest Disclosure Form." Each stakeholder completed and returned the disclosure prior to the individual interviews and completion of the Web-based questionnaires. Of the 30 stakeholders who agreed to participate, none declared significant conflicts of financial or professional/business interests. The research

team and the Agency for Healthcare Research and Quality (AHRQ) task order officer (TOO) reviewed all disclosures and identified no conflicts of interest that precluded participation in the project.

Phase 1: Identification of Evidence Gaps

In order to increase our understanding of the most critical research gaps, we conducted a series of 45- to 60-minute interviews with 16 stakeholders. Interviews were open ended and elicited stakeholder perspectives on priority areas for future research on VBAC as a whole. Given the limited body of existing research on Key Questions 1 and 2 from the evidence review, we placed particular emphasis on identifying potential research questions related to the patterns of utilization and nonmedical drivers of policy and practice on VBAC.

Telephone interviews were conducted individually or in groups of two to three. We provided each stakeholder with an electronic copy of the executive summary of the evidence review prior to the interview. At the beginning of each interview, the lead investigator reiterated the aims of the study and the overall findings of the 2010 evidence review and then gave respondents time to ask clarifying questions. Although we followed an interview guide tailored to each stakeholder perceptive (see Appendix C), the nature of the semistructured interview format intentionally left room for the stakeholders to influence the direction of the conversations. We were mindful throughout to emphasize our goal of identifying areas of research that would truly inform policy and practice. At the end of each interview, we described the prioritization process that would follow in phase 2 and asked whether stakeholders would be interested in taking part.

In the course of the interviews, we drew out barriers and challenges encountered in "real life experience" as much as possible. Questions focused on perceptions of the safety of trial of labor (TOL) and elective repeat cesarean delivery (ERCD), what information they do not have but would like to know in order to improve their policy or practice, and any barriers or facilitators they had encountered in providing access to safe TOL after cesarean. As appropriate, we included followup questions regarding institutional or policy-level factors, provider-level factors, and/or individual-level factors that might be influencing the patterns and utilization of TOL after cesarean. We elicited stakeholder perspectives on the impact of the 2010 VBAC evidence review, the National Institutes of Health (NIH) Consensus Development Conference, and the resulting change in American Congress of Obstetricians and Gynecologists (ACOG) recommendations on patterns and utilization of TOL after cesarean.

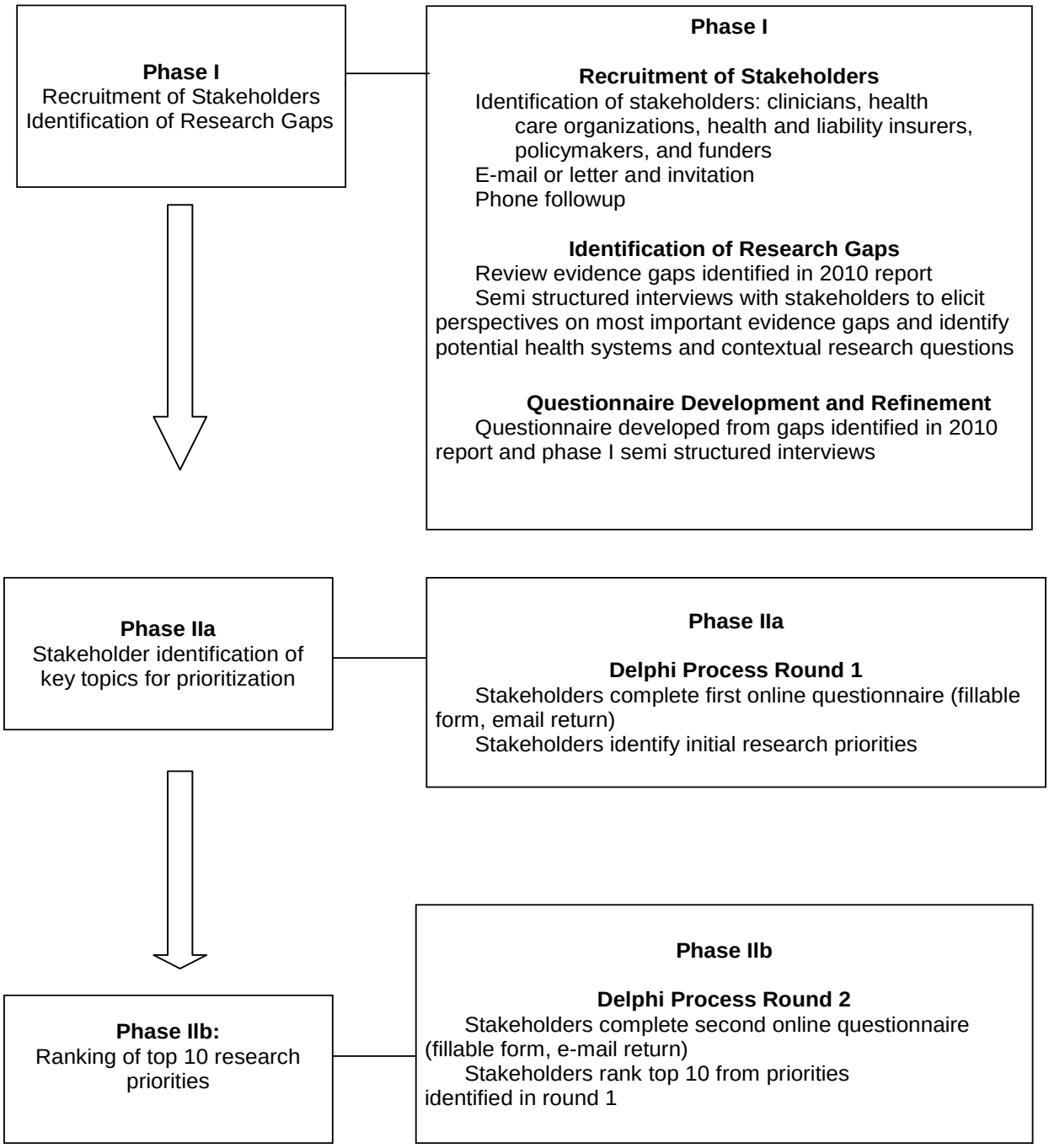
With the permission of the key informants, we recorded and transcribed the interviews. The transcripts were reviewed for common themes and key content areas by the lead investigator. Themes were reviewed and verified independently by a research associate and research assistant, who were both present for all interviews. The team discussed and resolved any discrepancies in identification of themes and key content areas as a group. In addition, the research team cross-referenced themes from the semistructured interviews with the evidence gaps identified in the 2010 evidence review, the NIH Consensus Development Conference, and recent literature on VBAC to identify areas that did not emerge during stakeholder interviews.

Questionnaire Development and Refinement

We developed two self-administered Web-based research prioritization questionnaires: one to select the initial top priorities (Questionnaire I; Appendix D), and a second to rank the top 10 research areas. The first questionnaire included the top 10 future research needs for Key

Questions 3–6 (as prioritized by experts during peer review of the 2010 VBAC report) as well as additional areas of future research, including the influence of contextual and nonmedical factors, identified through our stakeholder interviews. To assess comprehensiveness and usability of the instrument, we tested the initial questionnaire with a small (n~5) sample of individuals (two researchers, two clinicians, and one administrator) with perspectives similar to those of the stakeholder groups.

Figure 2. Study design



Phase 2: Prioritization of Evidence Gaps

Criteria for Prioritization

In phase 2 of the study, we used a modified Delphi process to prioritize the list of future research needs. Delphi is a technique increasingly used for reaching consensus on topics in medicine and education, including the prioritization of research topics. With this approach, a panel of stakeholders with relevant expertise was asked to prioritize topics in a series of questionnaires.[8] After each questionnaire, a summary of the group response was fed back to participants to reprioritize. The process was repeated until the group achieved an acceptable level of consensus. This approach enabled participants to consider the viewpoints of others and to reach consensus without the risk of domination by more senior or opinionated individuals. The electronic format enabled engagement of stakeholders from a range of geographical locations.

Round 1 of our Delphi process consisted of a 30-minute initial online questionnaire available from July 6–18, 2011. The Web-based tool was created and administered using Survey Monkey (© 1999–2010, San Jose, CA). Up to two electronic reminders, and when necessary, a followup phone call were used to remind participants to complete the questionnaire. The round 1 questionnaire consisted of 33 items related to prioritization of research areas, including both open-ended and structured questions, to identify priority research topics (see Appendix D Q1).

Because many of the identified research areas are cross-cutting and do not fit neatly into one PICO category, we arranged them into four overarching themes: health systems (nine questions); risk, attitudes, and decisionmaking (seven questions); shared decisionmaking and informed consent (five questions); and maternal and infant outcomes (12 questions). These four categories included the gaps identified during the 2010 evidence review as well as those identified during the semistructured interviews in phase 1.

For each of the structured questions, stakeholders were asked to indicate whether the topic was low, medium, or high priority for future research, and to provide narrative text to indicate additional detail on the types of research they recommended. At the end of the questionnaire, we provided a list of all 33 topics and asked respondents to choose the 10 highest priority areas. Respondents were instructed to use Effective Health Care (EHC) selection criteria—including burden of disease, high public interest, vulnerable populations, utilization of existing resources, and potential impact—when making their prioritizations.

In round 2 of the Delphi process, we emailed a list of the 15 highest priority items identified in round 1 and asked respondents to rank each from 1 to 10, with 1 being the highest priority. The questionnaire was sent electronically to participants on July 26, 2011 (Appendix E). Participants were asked to complete and return the second questionnaire by August 1, 2011. In making their rankings, respondents were asked to prioritize areas of research with the potential for immediate impact and to rate higher those areas that should be conducted first.

Analysis

Data were entered into Excel (© 2007, Microsoft, Seattle, Washington) for analysis. Distributions (frequency and percentage) of research prioritization were analyzed as a whole and by stakeholder perspective. For the structured questions, in round 1 we tabulated the number of times that the question was categorized as one of the top 10 priority research topics, as well as the number and proportion of high, medium, and low priority responses. Based on the number of

times a topic was selected as one of the 10 highest priorities and the percentage of high-priority rankings, clear top 15 priorities emerged.

In round 2 respondents were asked to rank the highest priority topics from 1 to 10, with 1 being the most important. They were instructed not to rank the five lowest priority topics. round 2 responses were weighted so that topics that received a number 1 ranking received a score of 10 and those with a number 2 ranking a score of 9, etc., with a ranking of 10 receiving a score of 1, and the five unranked topics receiving a score of 0. The scores were then placed into a table with rows consisting of the 15 research topics and columns consisting of individual stakeholder response scores. Finally, the scores for each research area were summed and the top 10 were identified and prioritized based on this score. Qualitative responses were tabulated by research priority and reviewed by the research team to determine if additional priorities not captured in the questionnaires were present. Results were analyzed for the stakeholder group as a whole, as well as by appropriate subgroups (e.g., researchers vs. funders) where numbers permitted, highlighting the top research domains for each. (See Table 1).

Identification of Completed and Ongoing Studies

To inform the continuing prioritization of future research in the top 10 prioritized areas we searched for active and completed research in each area and sought to identify relevant funding opportunities. To identify ongoing studies and recently completed research, a research librarian searched Scopus, Medline, the Annals of Internal Medicine Web site, Google Scholar, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Cochrane Database of Reviews of Effects (DARE), clinical trial registries, grant databases, and individual funders' Web sites. (For the detailed search strategy, see Appendix F.)

Results

Recruitment and Participation

Sixteen of 30 invited stakeholders agreed to participate in the phase 1 semistructured interviews (Figure 3). Overall, we conducted interviews with 6 of the 6 legal/liability or hospital administrators (100 percent); 2 of the 6 patient/consumer advocates (33 percent); 5 of the 13 clinicians (30 percent); 1 of the 2 researchers (50 percent); and 2 of the 3 research funders (66 percent) (Table 1). The category of clinician encompassed nurses, midwives, and physicians. In order to ensure a balance of these clinical perspectives a larger proportion of individuals were recruited from this stakeholder group.

Of the 16 stakeholders interviewed in phase 1, 11 were invited to take part in phase 2 of our study. Phase 2 consisted of two rounds of a Delphi process to identify the highest priority areas for future research. All stakeholders invited to participate in phase 2 completed the first round questionnaire and 10 of the 11 (81 percent) completed the second round questionnaire (Table 2). Of the stakeholders who participated in phase 2, one was a hospital administrator, two were patient/consumer advocates, five were clinicians, one was a researcher, and two were research funders. One of the research funders was unable to take part in the second round due to travel commitments.

We recognize that stakeholders often wear a number of hats. For the purposes of the phase 2 prioritization, we asked stakeholders to self report their primary perspective. Their self-reported perspectives were then compared with the perspective assigned by the research team to verify accuracy (Table 3). All but one of the self-identified perspectives matched up with that assigned by the research team. The one exception was a stakeholder who we classified as legal/liability and hospital administrator, but whose primary self-identified perspective was clinician. Because the stakeholder self-identified as a clinician and spoke primarily from the clinician perspective, we included the individual's results in the clinician category.

Figure 3. Recruitment and participation

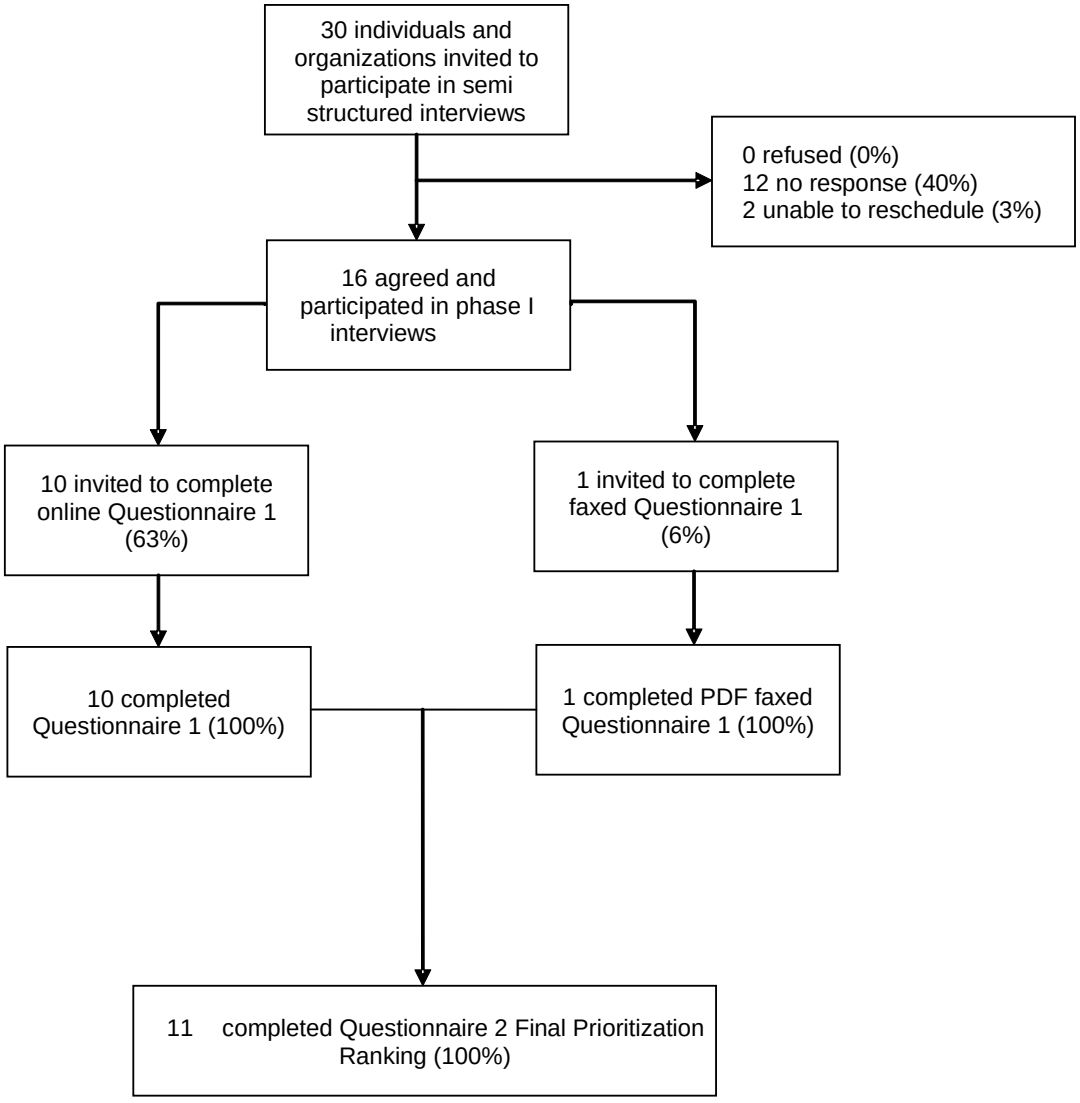


Table 1. Participants and organizations in phase 1

Stakeholders	Total Invited	Agreed	Participation Rate	Invited Organizations and Individuals
Legal/Liability and Hospital Administrators	6	6	100%	The Doctors Company; UCSF/UC Hastings Consortium on Law, Science & Health Policy; OHSU, Risk Management Department
Patient/Consumer Advocates	6	2	33%	National Advocates for Pregnant Women; Our Bodies Ourselves; ICAN; What to Expect Foundation
Clinicians	13	5	30%	Obstetricians, RNs, Nurse Midwives
Researchers	2	1	50%	NICHD; Office of Women's Health Maternal Fetal Medicine, Obstetrics and Gynecology, Northwestern University
Research Funders	3	2	66%	Pregnancy and Perinatology Branch, NICHD; Office of Research on Women's Health, NIH
Total	**30**	**16**	**53%**	

Table 2. Participants and organizations in phase 2

Stakeholders	Total Invited	Completed Round 1	Completed Round 2	Participation Rate	Participating Organizations and Individuals
Phase II, Delphi					
Legal/Liability and Hospital Administrators	1	1	1	100% (round 1) 100% (round 2)	The Doctors Company; UCSF/UC Hastings Consortium on Law, Science & Health Policy
Patient/Consumer Advocates	2	2	2	100% (round 1) 100% (round 2)	Our Bodies Ourselves; ICAN
Clinicians	5	5	5	100% (round 1) 100% (round 2)	Obstetricians, RNs, Nurse Midwives
Researchers	1	1	1	100% (round 1) 100% (round 2)	Pregnancy and Perinatology Branch, NICHD; Office of Interdisciplinary Research Programs; Office on Women's Health; Maternal Fetal Medicine, Obstetrics and Gynecology, Northwestern University
Research Funders	2	2	1	100% (round 1) 50% (round 2)	Pregnancy and Perinatology Branch, NICHD; Office of Research on Women's Health, NIH
Total	**11**	**11**		**100% (round 1) 91% (round 2)**	

Table 3. Team-assigned and self-identified perspectives of stakeholders: phase 2 Web questionnaire

Respondent	Perspective Assigned	Perspective Chosen
1	Clinician	Clinician
2	Research Funder	Research Funder
3	Consumer Advocate	Consumer Advocate
4	Researcher	Researcher
5	Clinician	Clinician
6	Legal/Liability or Hospital Administration	Lawyer, Law Professor
7	Consumer Advocate	Consumer Advocate
8	Legal/Liability or Hospital Administration	Clinician
9	Clinician	Clinician
10	Research Funder	Research Funder
11	Clinician	Clinician

Phase 1

Data from the series of semistructured stakeholder interviews along with evidence gaps identified in the 2010 evidence review were organized into four overarching thematic categories. The four categories included: (1) health systems; (2) risk, attitudes, and decisionmaking; (3) shared decisionmaking and informed consent; and (4) clinical outcomes for mother and infant. Gaps identified during the 2010 evidence review are integrated into these categories. In analyzing the data from the interviews, we attempted to frame evidence gaps in terms of potential research questions.

The evidence gaps and related research questions identified in phase 1 are listed below.

Contextual and health system delivery factors:

1. Research on barriers to providing safe trial of labor (TOL), including factors that limit the availability of hospitals to meet the "immediately available" requirement (i.e., availability of anesthesiologists, obstetric providers, and other resources).
2. Studies to test clinical, institutional, or policy interventions to increase access to safe TOL.
3. Studies to understand best practice models based on institutions that are currently offering TOL.
4. Studies to test the effectiveness of simulation training for increasing capacity to offer safe TOL.
5. Clinical and policy relevant studies to address the threat of legal liability on patterns and utilization of TOL (vs. ERCD [elective repeat cesarean delivery]).
6. Studies of the influence of Medicaid policy and private insurance reimbursement on availability of TOL (vs. ERCD).
7. Studies that correlate benefits and harms of VBAC (vaginal birth after cesarean) and ERCD with short- and long-term health system costs.
8. Research on the threshold/tipping point for a change in health policy in response to harms compared with benefits.

9. Studies on the influence of VBAC policies on trends in home births.

Risk, attitudes, and decisionmaking:

1. Research on how *patients* understand risk, how they respond to different ways of framing risk, and how best to communicate risks of TOL compared with ERCD.
2. Research on how *providers* understand risk, how they respond to different ways of framing risk, and how best to communicate risks of TOL compared with ERCD.
3. Research on how *health system administrators and liability companies* understand risk, how they respond to different ways of framing risk, and how best to communicate risks of TOL compared with ERCD.
4. Studies of the factors shaping *patient* attitudes and decisionmaking on TOL.
5. Studies of the factors shaping *provider* attitudes and decisionmaking on TOL.
6. Studies of the factors shaping *health system administrator and liability company* attitudes and decisionmaking on TOL.
7. Research on the relationship between fear of childbirth and decisionmaking surrounding mode of delivery.

Shared decisionmaking and informed consent:

1. Studies to understand whether and how patients and providers can work together to make a shared decision about TOL compared with ERCD.
2. Studies comparing the efficacy of different types of decision aids for TOL compared with ERCD.
3. Studies on the timing of administering decision aids or providing other information about the risks and benefits of TOL compared with ERCD (i.e., after a woman's first cesarean birth compared with waiting until her next pregnancy).
4. Studies of how women are consented for both TOL and ERCD and whether consent encompasses risks to current and future pregnancies.
5. Studies to refine, validate, and implement informed consent templates that are informative, reliable and able to be well documented.

Maternal and infant outcomes:

1. Development of standardized measures for short- and long-term maternal and infant outcomes.
2. Population-level research on patterns of utilization and maternal/infant outcomes of VBAC, TOL with emergent cesarean, and ERCD – stratified by race/ethnicity and socioeconomic status.
3. Development/utilization of a reliable model or tool to predict the probability of successful TOL for individual women.
4. Development of registries to track the frequency and safety of home births, including TOL.
5. Comparative studies of *type of provider* (obstetrician, midwife, family practice physician) on patterns of utilization and maternal/infant outcomes of TOL compared with ERCD.
6. Comparative studies of *delivery setting* (tertiary care center, community hospital, free standing birth center, at home) on patterns of utilization and maternal/infant outcomes of TOL compared with ERCD.

7. Investigation of whether antepartum or intrapartum management strategies (such as labor induction) influence rate of TOL compared with ERCD and maternal/infant outcomes.
8. Studies comparing outcomes for mother and infant in settings where physicians are "immediately available" compared with settings where physicians are "readily available."
9. Comparison of risk of maternal or infant adverse outcomes during childbirth in general compared with risk of adverse outcomes with TOL or ERCD.
10. Studies to compare the affect of TOL compared with ERCD on breastfeeding initiation and continuation.
11. Studies to compare the affect of TOL compared with ERCD on psychosocial outcomes such as maternal-infant bonding and postpartum depression.
12. Surveillance to determine long-term maternal and infant clinical outcomes of TOL compared with ERCD.

Phase 2

Questions for the first round of the phase 2 prioritization were based on the categories and themes (listed above) that were identified in phase 1. Participants were asked both to (1) rate each evidence gap/research question as high, medium, or low priority and (2) select the 10 highest priority items from the entire list. Respondents were asked to consider criteria such as burden of disease, high public interest, vulnerable populations, utilization of existing resources, and potential impact in making their selections.

After tabulating the number of times that each topic was included as one of the 10 highest priorities and the percentage of respondents who ranked each topic as high, medium, or low priority (Table 4), 15 topics emerged as the top priorities from the first round of the questionnaire. The top 15 priorities are highlighted in bold in Table 4 below. (See Appendix E for the list of topics for prioritization as presented to stakeholders). There was a natural break between the top 15 topics (40–70 percent of respondents included in their top 10) and the remaining 18 topics (30 percent or fewer respondents included in their top 10). We cross referenced the results of the high/medium/low and top 10 rankings to identify any discrepancies. These results were remarkably consistent, with the exception of question 7 (studies that correlate benefits and harms of VBAC and ERCD with short- and long-term health system costs), which was rated high by 63.6 percent of respondents but was only included in one respondent's top 10 research priorities. In other words, although seven respondents ranked question 7 as high priority, when choosing the 10 highest priority questions, only one included question 7.

Table 4. Phase 2, Delphi round 1: detailed responses

Question [a]	High (%) (n)	Medium (%) (n)	Low (%) (n)	Times Ranked in Top 10
Section IIA: Health System Factors				
Q1. Research on barriers to providing safe TOL, including factors that limit the ability of hospitals to meet the "immediately available" requirement (i.e. availability of anesthesiologists, availability of obstetric providers, other resources)	72.7% (8)	18.2% (2)	9.1% (1)	7
Q2. Studies to test clinical, institutional, or policy interventions to improve safety and availability of TOL	63.6% (7)	18.2% (2)	18.2% (2)	6

Table 4. Phase 2, Delphi round 1: detailed responses (continued)

Question [a]	High (%) (n)	Medium (%) (n)	Low (%) (n)	Times Ranked in Top 10
Q3. Studies to understand best practice models based on institutions that are currently offering safe TOL	72.7 % (8)	18.2% (2)	9.1% (1)	4
Q4. Studies to test the effectiveness of simulation training in increasing capacity to offer safe TOL	18.2% (2)	36.4% (4)	45.5% (5)	2
Q5. Clinical and policy relevant studies to address the threat of legal liability on practice patterns regarding TOL vs. ERCD	45.5% (5)	9.1% (1)	45.5% (5)	4
Q6. Studies of the influence of Medicaid policy and private insurance reimbursement on availability of TOL after cesarean vs. ERCD	18.2% (2)	36.4% (4)	45.5% (5)	2
Q7. Studies that correlate benefits and harms of VBAC and ERCD with short- and long-term health system costs	63.6% (7)	36.4% (4)	0 (0)	1
Q8. Research on the threshold/tipping point for a change in health policy in response to harms vs. benefits	27.3% (3)	54.5% (6)	18.2% (2)	0
Q9. Studies on influence of VBAC policies on trends in home births	9.1% (1)	36.4% (4)	54.5% (6)	0
Section IIB: Risk, Attitudes, and Decisionmaking				
Q10. Research on how *patients* understand risk, how they respond to different ways of framing risk, and how best to communicate risks of TOL vs. ERCD	60.0% (6)	30.0% (3)	10.0% (1)	6
Q11. Research on how *providers* understand risk, how they respond to different ways of framing risk, and how best to communicate risks of TOL vs. ERCD	63.6% (7)	36.4% (4)	0 (0)	7
Q12. Research on how *health system administrators & liability companies* understand risk, how they respond to different ways of framing risk, and how best to communicate risks of TOL vs. ERCD	45.5% (5)	36.4% (4)	18.2% (2)	5
Q13. Studies of the factors shaping *patient* attitudes and decisionmaking on TOL after cesarean	60.0% (6)	20.0% (2)	20.0% (2)	3
Q14. Studies of the factors shaping *provider* attitudes and decisionmaking on TOL after cesarean	60.0% (6)	30.0% (3)	10.0% (1)	6
Q15. Studies of the factors shaping *health system administrator & liability company* attitudes and decisionmaking on TOL after cesarean	40.0% (4)	30.0% (3)	30.0% (3)	4
Q16. Research on the relationship between fear of child birth and decisionmaking surrounding mode of delivery	10.0% (1)	20.0% (2)	70.0% (7)	1
Section IIC: Shared Decisionmaking and Informed Consent				
Q17. Studies to understand whether and how patients and providers work together to make a shared decision about TOL vs. ERCD	40.0% (4)	30.0% (3)	30.0% (3)	2
Q18. Studies comparing the efficacy of different types of decision aids for TOL vs. ERCD	40.0% (4)	50.0% (5)	10.0% (1)	3
Q19. Studies on the timing of decision aids or other information about the risks and benefits of TOL vs. ERCD (i.e. after the woman's first cesarean vs. waiting until her next pregnancy)	20.0% (2)	40.0% (4)	40.0% (4)	3
Q20. Studies of how women are consented for both TOL after previous cesarean and ERCD and whether consent encompasses risks to current and future pregnancies	45.5% (5)	36.4% (4)	18.2% (2)	4

Table 4. Phase 2, Delphi round 1: detailed responses (continued)

Question [a]	High (%) (n)	Medium (%) (n)	Low (%) (n)	Times Ranked in Top 10
Q21. Studies to refine, validate, and implement informed consent templates that are informative, reliable, and able to be well documented	36.4% (4)	45.5% (5)	18.2% (2)	4
Section IID: Maternal and Infant Outcomes				
Q22. Development of standardized measures for short- and long-term maternal and infant outcomes	36.4% (4)	54.5% (5)	9.1% (1)	4
Q23. Population-level research on patterns of utilization and maternal/infant outcomes of VBAC, TOL with emergent cesarean, and ERCD, stratified by race/ethnicity and socioeconomic status	27.3% (3)	36.4% (4)	36.4% (4)	2
Q24. Development/utilization of a reliable model or tool to predict the probability of successful VBAC for individual women	63.6% (7)	27.3% (3)	9.1% (1)	5
Q25. Development of registries to track frequency and safety of home births, including TOL after cesarean	18.2% (2)	36.4% (4)	45.5% (5)	1
Q26. Comparative studies of *type of provider* (OB/GYN, midwife, family practice physician) on patterns of utilization and maternal/infant outcomes of TOL vs. ERCD	36.4% (4)	45.5% (5)	18.2% (2)	1
Q27. Comparative studies of *delivery setting* (tertiary care center, community hospital, free standing birth center, at home) on patterns of utilization and outcome of TOL vs. ERCD	36.4% (4)	45.5% (5)	18.2% (2)	3
Q28. Investigation of whether antepartum or intrapartum management strategies – such as labor induction – influence rate of TOL vs. ERCD and maternal/infant outcomes	45.5% (5)	36.4% (4)	18.2% (2)	2
Q29. Studies comparing outcomes for mother and infant in settings where physicians are "immediately available" vs. settings where physicians are "readily available"	70.0% (7)	10.0% (1)	20.0% (2)	5
Q30. Comparison of risk of maternal or infant adverse outcomes during childbirth in general vs. TOL or ERCD	30.0% (3)	50.0% (5)	20.0% (2)	2
Q31. Studies to compare impact of TOL vs. ERCD on breastfeeding initiation and continuation	10.0% (1)	50.0% (5)	40.0% (4)	1
Q32. Studies to compare impact of TOL vs. ERCD on psychosocial outcomes such as maternal-infant bonding and post-partum depression	30.0% (3)	40.0% (4)	30.0% (3)	0
Q33. Surveillance to determine long-term maternal and infant clinical outcomes of TOL vs. ERCD	60.0% (6)	30.0% (3)	10.0% (1)	4

ERCD, elective repeat cesarean delivery; OB/GYN, obstetrician/gynecologist; TOL, trial of labor; VBAC, vaginal birth after cesarean

[a] Bolded questions denote those that were selected as a Top 15 research priority in phase 2, round 1.

In order to come to a more definitive consensus on the top 10 research priorities, in a second round stakeholders were asked to rank the top 10 research priorities from the 15 highest priority areas generated in round 1 (top 15 priorities are bolded in Table 4 above and listed in Appendix E). Respondents were instructed to reflect on the topics they believed were the highest priority, both in terms of potential impact and urgency, and to rank them from 1 to 10, with 1 being the most important. The bottom five priorities did not receive a ranking. A weighted score was calculated for each area, with higher rankings given greater weight than lower rankings (i.e., 1=10 points, 2=9 points, 3=8 points, 4=7 points, 5=6 points, 6=5 points, 7=4 points, 8=3 points,

9=2 points, 10=1 point, not ranked=0 points). Using this system of tabulation, a final ranked list emerged (Table 5).

Table 5. Phase 2, Delphi round 2: top 10 VBAC future research priorities

Priority	Final Rank	Weighted Score[a]	Category of Research
Studies to test clinical, institutional, or policy interventions to increase access to "safe" TOL	**1**	72	A
Research on barriers to providing safe TOL, including factors that limit hospitals' ability to meet the "immediately available" requirement (i.e., availability of anesthesiologists, obstetric providers, and other resources)	**2**	51	A
Studies comparing outcomes for mother and infant in settings where physicians are "immediately available" vs. settings where physicians are "readily available"	**3**	46	A
Studies to understand best practice models based on institutions that are currently offering safe TOL	**4**	41	A
Development of standardized measures for short-and long-term maternal and infant outcomes	**5**	41	B
Surveillance to determine long-term clinical outcomes of TOL vs. ERCD	**6**	38	B
Research on how patients understand risk, how they respond to different ways of framing risk, and how best to communicate risks of TOL vs. ERCD	**7**	37	C
Clinical and policy relevant studies to address the threat of legal liability on practice patterns regarding TOL vs. ERCD	**8**	34	A
Development/utilization of a reliable model or tool to predict the probability of successful VBAC for individual women and/or a tool to predict probability of successful VBAC in general	**9**	32	B
Studies to refine, validate, and implement informed consent templates that are informative, reliable, and able to be well documented	**10**	26	C

ERCD, elective repeat cesarean delivery; TOL, trial of labor; VBAC, vaginal birth after cesarean
[a] Weighted scores correspond to the prioritized ranking in the second round of phase 2

Research Needs

The top 10 research questions arising from the phase 2 prioritization are listed in Table 5. The identified research priorities clustered into three overarching categories: health systems and contextual issues (category A in Table 5), standardized measurement and collection of data on maternal and infant outcomes (category B in Table 5), and understanding how patients perceive risk and how best to communicate risk of mode of delivery after prior cesarean (category C in Table 5). In synthesizing the results it is helpful to discuss each topic in the context of these categories. A brief discussion of each research priority is included in the text below. Potential study designs and information about ongoing and completed research in each area are listed in Table 6.

Overall, stakeholders felt that defining what constitutes a "safe" TOL after cesarean, and a safe birth in general, at the level of the individual, the provider, and the institution or setting of care was important across all top priority research needs. As summed up by one of our stakeholders: "An important potential dilemma is defining what constitutes 'safe' TOL, in whose judgment is TOL 'safe' and where the 'immediately available' standard fits in that definition or

if it even is an appropriate factor in the definition. Once safe is defined, find best practices [for] achieving it and test them in other settings."

Health Systems and Contextual Issues

Priority 1. Studies to test institutional or policy interventions to improve safety and availability of TOL after cesarean

In-depth interviews with stakeholders and review of the literature revealed that very little is known about what constitutes a safe environment for TOL after cesarean (the pros and cons of different settings and environments) and what institutional or policy interventions and/or best practices might contribute to the creation of a safe environment.[9] Stakeholders also highlighted the need for research on whether the same types of interventions are applicable among different types of providers or in different institutional settings.

> "…the epidemiology of VBAC at this point is well known…it couldn't be more consistent….we don't need any more [epidemiological] studies…. We've got enough…so I think at this point it's about health care services... and outcomes research and trying to figure out how services…can be effectively disseminated to the community, be made available to women and made available in such a way that women are actually receiving the health care that they desire."

Priority 2. Research on barriers to providing safe TOL after cesarean, including factors that limit the ability of hospitals to meet the "immediately available" requirement (i.e., availability of anesthesiologists, availability of obstetric providers, and availability of other resources)

Stakeholders frequently mentioned the "immediately available" phrase from the American Congress of Obstetricians and Gynecologists (ACOG) guideline, which states that "because of the risks associated with TOL after cesarean and that uterine rupture and other complications may be unpredictable, the College recommends that TOL after cesarean be undertaken in facilities with staff immediately available to provide emergency care."[10] Stakeholders suggested that an inability of hospitals to meet the "immediately available" requirement is one of the primary barriers to offering access to safe TOL after cesarean. In addition to the immediate availability of obstetric providers, the availability of anesthesiologists was pinpointed as a critical barrier. Many stakeholders also discussed the fact that there is wide variation in the way that different institutions interpret the meaning of "immediately available." For example, there is little evidence regarding how rural hospitals manage VBAC risk in cases where a shortage of anesthesiologists limits the ability to provide around-the-clock "immediately available" staff. Stakeholders highlighted the need for further exploration into how the "immediately available" requirement is understood and implemented, barriers to achieving this standard, and other obstacles to providing access to safe TOL.

> "It's important! We need to focus on the requirements for the 'team' not 'just' the provider, including how the finances could work."

> "I also feel that the other important issue is how hospitals are interpreting 'immediately available.' I've had small hospitals in my State retain VBAC while larger ones stopped doing it and so feel that the issue has never strictly been one of resource allocation. Is having an OB

across the street from the hospital conducting his/her office hours 'immediate'? Is having one asleep in the doctor's sleeping lounge one floor above the L&D unit enough? Never in my doula work have I witnessed an OB or anesthesiologist standing guard outside of a laboring woman's hospital room in order to be 'immediately available' in case of an emergency."

Priority 3. Studies comparing outcomes for mother and infant in settings with "immediately available" compared with "readily available" providers

As mentioned above, stakeholders recognized the "immediately available" requirement as a critical barrier to offering TOL after cesarean. Yet they also pointed to the lack of evidence on the difference in outcomes for mothers and babies in settings where providers are "immediately" compared with "readily" available. To facilitate such this type of research, stakeholders emphasized the need to correlate data on maternal and infant outcomes with hospital level indicators including hospital size, staffing structures, facility resources and capacity, participation in hospital systems and networks, business models, malpractice insurance and carrier restrictions.[9] In the words of one of our stakeholders:

"….this would be a very critical study since most hospitals are influenced by ACOG's guidelines. If research finds that outcomes are the same, there would be no basis to support ACOG's requirement. Risk managers and insurance companies would still need ACOG to revise their guidelines."

Priority 4. Studies to understand best practice models for safe TOL after cesarean

Stakeholders reported a number of examples of institutions that are successfully providing access to safe TOL after cesarean. They pointed to a need for in-depth studies of what factors enabled these institutions to provide safe TOL after cesarean and what aspects of their practices can be replicated in other settings as well as a comparison of best practices in a variety of settings and hospital types. In particular, stakeholders suggested developing best practice models for institutions that "do not meet the immediately available guideline," and stratifying best practice models by hospital size.

Priority 8. Clinical- and policy-relevant studies to address the threat of legal liability on practice patterns regarding TOL compared with ERCD

There was wide consensus among the stakeholders interviewed that legal liability is a key driver of the decision to offer TOL after cesarean at both the institutional and provider levels. The perceived risk of malpractice claims and lawsuits are thought to influence clinician behavior, particularly related to cesarean section. Stakeholders highlighted the need for more reliable data to examine the extent that liability concerns are driving practice at both the institutional and provider level.

"It is widely assumed that the VBAC problem will not be resolved without liability reform. It would be useful to get more good data on the real extent to which litigation fears drive provider/hospital choices….if it could be documented that these fears are a main factors, this can support reform efforts. If it is found that they're not really the heart of the problem, the myth can be debunked and efforts redirected."

"But what isn't an urban myth, but is the more sort of fuzzy thing, is the sense that it is taking on a professional liability burden and that even if you undertake a trial of labor and kind of do all the right things, if there's a bad outcome, that you may be sued for that…."

Standardized Measurement and Collection of Data on Maternal and Infant Outcomes

Priority 5. Development of standardized measures for short- and long-term maternal and infant outcomes

Integral to future decisionmaking at all levels is identification of the most meaningful short- and long-term maternal and infant outcomes and agreement on clear and precise definitions and methods of ascertainment. Stakeholders identified the importance of standardization of definitions as well as methods for measuring and reporting. In addition, as highlighted above further data collection at the hospital level is required in order to develop a more comprehensive understanding of the impact of institutional structure and management on maternal and infant outcomes.

"This is the foundation of all future decisionmaking. Number one priority!"

Priority 6. Surveillance to determine long-term clinical outcomes of delivery after previous cesarean

Most studies focus on short- rather than long-term complications of delivery after previous cesarean. Better understanding of the long-term outcomes comparing TOL with ERCD is needed, particularly in order to inform women's choices—especially among those who will have future pregnancies. Women who have a cesarean delivery have an increased risk of a range of chronic conditions and may be at increased risk for infertility or subfertility. Women who undergo multiple cesarean deliveries have a higher risk of morbidity and mortality from placenta accreta.[11]

In addition, future studies should include a range of reproductive outcomes, including postpartum depression and quality of life. Outcomes that affect both mother and infant, such as those related to breastfeeding and parental attachment, have not been studied in relation to VBAC.

"Clearly needed, especially long-term outcome data."

"Include maternal information on future pregnancies."

Priority 9. Development/utilization of a reliable model or tool to predict probability of successful VBAC for individual women

The 2010 evidence review identified gaps in the ability of existing prediction tools to select women for a successful TOL after cesarean. Improvements in current prediction tools could be made, which necessitates the collection of standardized data and development of a better understanding of what factors contribute to the probability of a successful TOL in different settings. Prediction tools should be designed to encompass nonmedical factors associated with a successful or failed TOL, the impact of different labor management strategies (such as induction of labor), and whether there are differences among racial, ethnic, or socioeconomic groups.

"This could be used to improve risk stratification, which is a promising candidate for 'best practice.' "

"The proposed model would not be accurate since what we see from the consumer side is the probability of success being vastly dependent on the type of care provider the woman uses (midwife vs. OB) and birth location."

Understanding How Patients Perceive Risk and How Best To Communicate Risk of Mode of Delivery After Prior Cesarean

Priority 7. Research on how *patients* understand risk, how they respond to different ways of framing risk, and how best to communicate risks of TOL compared with ERCD

Stakeholders identified patient decisionmaking on route of delivery after cesarean as a particular challenge, especially given the recommendation of the 2010 ACOG guidelines that women are engaged in a shared decisionmaking process. In addition to considering the short- and long-term benefits and risks of route of delivery for their current and future pregnancies, patients are also influenced by family obligations, costs, societal norms, and regional availability of options. Stakeholders described an overall lack of understanding how patients are making decisions about TOL compared with ERCD, how they perceive the risks of TOL compared with ERCD, and how their perception of risk influences their decision. They emphasized the need for a more complete and nuanced understanding of how best to present information so that women can make a truly informed choice that incorporates their preferences.

"Need pictures, visible info—patients forget what you tell them in an office visit. Need something they can take home, or do on Web…."

"I regard the entire risk assessment/understanding/communication aspect [as] highly important. Especially for patients and providers, less so for administrators and liability companies."

"We have no idea about how women actually make this decision. We have no idea. You [need to] know…what they value…their ways to assess…different health states and health processes and how women value what they incorporate. For that woman who chooses a trial of labor, why does she do that? Why does one woman choose it at a 1 in 300 chance or a perceived 1 in 1,000 chance of [harms]… why does one woman look at one in a thousand and think that's crazy and another woman look at a 1 in 1,000 risk of perinatal harm and think, 'oh, why are you even talking to me about something that's so rare?' Or two women with a 70 percent chance of success, one chooses an elective repeat and one chooses a trial of labor? I mean what [factors] are driving their decisions? What do they value? We have no idea."

Priority 10. Studies to refine, validate and implement informed-consent templates that are informative, reliable, and able to be well documented

In addition to studies of how women perceive risk and how they make decisions regarding TOL after cesarean, stakeholders prioritized further exploration of how best to ensure detailed

and truly informed consent. Because providers differ in their perception of the risk of TOL after cesarean and the actual risk and benefit profile differs for individual women, ensuring truly informed consent is a complex task. In addition, clinicians emphasized the need for a standardized way of providing informed consent endorsed by ACOG or another institutional body. However, stakeholders also pointed out that in addition to developing standardized informed consent templates, there also needs to be agreement on the part of liability companies that evidence of informed consent would be considered in liability cases.

> "That would be great to have a national standard. Something 'blessed' by ACOG would be great."

> "I would give this a higher priority if the liability companies indicate that this would be of benefit to them. What we hear physicians stating is that having a signed consent form 'doesn't matter anyways' when it comes to being sued."

Future Research Agenda: Potential Study Designs and Ongoing or Recently Completed Research

Table 6 lists the top 10 future research priorities identified by stakeholders along with suggestions for potential study designs and references to ongoing and completed research relevant to each topic. Potential study designs for each priority area were derived from discussions with stakeholders during semistructured interviews conducted in phase 1 and further developed and informed by research design principles. The suitability of a research design for a research topic depends on a number of factors, including the intent and objectives of the research, how much is already known about the topic in question, and the desired balance between a controlled versus "real world" setting. As evidence in a body of research is gathered, research designs generally progress along a continuum from exploratory to descriptive to causal (or experimental). For example, when little is known about a given topic, exploratory studies are employed to provide insight, increase our understanding of relevant variables and explore and develop hypotheses. Once a body of exploratory research is established, descriptive studies based on observational data provide a map of the patterns and relationships among key variables in a larger context. Next, causal or experimental research attempts to uncover cause and effect relationships by manipulating key independent variables either through investigator controlled or natural experiments.

Because this future research needs agenda extends beyond traditional clinical research into health systems and policy, we expand the nomenclature used to describe potential study designs to include behavioral and policy research in addition to clinical and health services research. A notable distinction in the study design nomenclature in clinical versus policy research is the use and understanding of the term case study. A case study in clinical research describes a study or report of individual patient or case. In contrast, the unit of analysis for a case study in policy research can be an institution, a state or even an entire country as the case refers to a case of policy and the outcome is the impact upon a population. In order clearly to make this distinction, we refer to the latter as "policy case studies" in Table 6.

We identified 98 ongoing or recently completed studies related to VBAC since the publication of the evidence review in 2010, through a search of clinical trial registries, grant databases, and individual funders' Web sites (see Methods: Identification of Ongoing Studies).

Few of the ongoing studies related to VBAC addressed the priority research areas identified by stakeholders. Among these, only six ongoing studies were identified that inform at least one of the top 10 prioritized topics. Two studies addressed the health systems issues. In particular, a Dutch study[12] assessed barriers to the implementation of TOL, and a study by Roth[13] explored the threat of legal liability on practice patterns regarding TOL compared with ERCD (research area A). Two studies evaluated long-term clinical outcomes of TOL compared with ERCD (research area B).[14,15] In addition, two studies investigated patient preferences and decisionmaking, information that may add to our understanding of how patients understand risk, and how best to communicate risks of TOL compared with ERCD (research area C).[16]

Table 6. Future research agenda for vaginal birth after cesarean

Ranked Priority	Research Area	Potential Study Designs	Ongoing Research[a]	Completed Research[a]
Research Area A. Health systems and contextual issues				
1	Studies to test clinical, institutional, or policy interventions to increase access to "safe" TOL after cesarean	Exploratory, descriptive and causal studies, including: • Analysis of observational data • Policy case studies[b] • Surveys of clinicians, policymakers and administrators • Focus groups/interviews • Natural experiments or ecological studies among communities with differing medical resources/settings Once there is a body of evidence on the efficacy of different interventions, experimental studies could be conducted to test their effectiveness in different settings and/or compare the effectiveness of different interventions		9, 17, 18
2	Research on barriers to providing safe TOL, including factors that limit the ability of hospitals to meet the "immediately available" requirement	Exploratory, descriptive and causal studies, including: • Analysis of observational data • Policy case studies[b] • Surveys of clinicians, policymakers, and administrators • Focus groups/interviews • Natural experiments or ecological studies among communities with differing medical resources/ settings	12	

Table 6. Future research agenda for vaginal birth after cesarean (continued)

Ranked Priority	Research Area	Potential Study Designs	Ongoing Research[a]	Completed Research[a]
3	Studies comparing outcomes for mother and infant in settings where physicians are "immediately available" vs. settings where physicians are "readily available"	Exploratory, descriptive and causal studies, including: • Analysis of observational data • Policy case studies[b] • Focus groups/interviews • Surveys of patients, clinicians, and administrators • Natural experiments or ecological studies among communities with differing medical resources/ settings		19
4	Development of best practice models based on institutions that are currently offering safe TOL	Exploratory and descriptive studies, including: • Analysis of observational data • Policy case studies[b] • Surveys of clinicians, policymakers and administrators • Focus groups/interviews		
8	Clinical and policy-relevant studies to address the threat of legal liability on practice patterns regarding TOL vs. ERCD	Exploratory, descriptive and causal studies, including: • Analysis of observational data • Policy case studies[b] • Surveys of clinicians, policymakers and administrators • Focus groups/interviews • Natural experiments or ecological studies among communities with differing medical resources/settings • Meta-analysis of observational data	13	19, 20

Table 6. Future research agenda for vaginal birth after cesarean (continued)

Ranked Priority	Research Area	Potential Study Designs	Ongoing Research[a]	Completed Research[a]
Research Area B. Standardized measurement and collection of data				
5	Development of standardized measures for short- and long-term maternal and infant outcomes	Exploratory and descriptive studies, including: • Analysis of observational data • Reviews, case reports • Focus groups/interviews with administrators, clinicians and patients Research should also investigate measures to capture systems and process factors that contribute to safety and quality to inform research gaps outlined in priorities 1-4		19, 21
6	Surveillance to determine long-term clinical outcomes of TOL vs. ERCD	Descriptive studies, including: • Analysis of observational data • Cohort studies • Analysis of registry data Development of standardized measures described in priority 5 will facilitate the collection of the most appropriate clinical outcomes as well as process and systems indicators of quality and safety	14, 15	22-25
9	Development/utilization of a reliable model or tool to predict the probability of successful VBAC for individual women	Descriptive and causal studies, including: • Analysis of observational data • Meta-analysis of observational data • Modeling		
Research Area C. Understanding and communicating risk of TOL after cesarean vs. ERCD				
7	Research on how *patients* understand risk, how they respond to different ways of framing risk, and how best to communicate risks of TOL vs. ERCD	Exploratory, descriptive and causal studies, including: • Focus groups/interviews of patients • Surveys of patients and providers • Development of decision aids • Randomized trials to test different types of decision aids	16, 26	

Table 6. Future research agenda for vaginal birth after cesarean (continued)

Ranked Priority	Research Area	Potential Study Designs	Ongoing Research[a]	Completed Research[a]
10	Studies to refine, validate, and implement informed consent templates that are informative, reliable, and able to be well documented	Exploratory, descriptive and causal studies, including: • Focus groups/interviews • Surveys of patients, clinicians, administrators, liability companies • Randomized trials to test informed consent templates		27

[a] Numbers indicate citations (see Reference section) of ongoing/completed research since the evidence review in 2010.
[b] Whereas a case study in clinical research describes an individual patient or case, the unit of analysis for a case study in policy research is an institution, a state or even an entire country and the outcome is the impact upon a population. In order clearly to make this distinction, we refer to the latter as "policy case studies."
ERCD, elective repeat cesarean delivery; SES, socioeconomic status; TOL, trial of labor; VBAC, vaginal birth after cesarean

Discussion

The purpose of this project was to engage a panel of national stakeholders to identify and prioritize future research needs in the area of vaginal birth after cesarean (VBAC). The 2010 evidence review included an initial prioritization of research gaps for the four Key Questions (Key Questions 3–6) relating to maternal and infant health outcomes. However, because of the limited body of evidence and focus of the Conference on questions 3–6, research gaps relating to the first two questions on practice patterns, trends, and nonmedical factors were not prioritized by the original review. The evidence review and the National Institutes of Health (NIH) Consensus Development Conference Statement identified numerous factors that play an important role in decisionmaking and patient access to trial of labor (TOL) after cesarean—including professional liability concerns, professional and institutional policies, patient insurance type, and provider and patient attitudes.[6,7] Yet they found relatively few studies devoted to understanding the influence of such nonmedical factors on the patterns and utilization of VBAC and a limited evidence base from which to prioritize future research in this area.[5] Accordingly, in the first phase of this project, we engaged a diverse panel of stakeholders to explore potential research needs for the first two questions relating to nonmedical factors shaping patterns of utilization. In the second phase, we engaged a smaller subset of stakeholders to prioritize potential research questions across all of the six evidence review questions to provide a full spectrum of future research needs relating to VBAC.

Half of the top 10 VBAC future research needs prioritized as important by stakeholders fall into the category of health systems or contextual issues. In the words of one of our stakeholders, "The epidemiology of VBAC at this point is well known…it couldn't be more consistent….We don't need any more [epidemiological] studies…. We've got enough…so I think at this point it's about health care services... and outcomes research and trying to figure out how services…can be effectively disseminated to the community, be made available to women and made available in such a way that women are actually receiving the health care that they desire." Moreover, stakeholders felt that defining what constitutes a "safe" TOL after cesarean, and a safe birth in general, at the level of the individual, the provider, and the institution or setting of care was an important consideration across all top priority research needs.

There are challenges inherent to conducting research on the role of health systems and contextual factors in the delivery and conduct of maternity care. As highlighted in the National Institutes of Health (NIH) Consensus Development Conference Statement, currently there are few data available to judge the relative impact and interaction of nonmedical factors on decisionmaking about and access to TOL.[3] Consequently, initial studies will likely be exploratory and descriptive and may need to rely on nontraditional methods including qualitative interviews, case studies or natural experiments.

Ultimately, the ability to conduct large-scale studies in this area hinges on the development of standard terminology and indicators to measure nonmedical outcomes and process measures that influence TOL decisionmaking and access. Historically, the quest to develop standardized obstetric indicators has not been an easy task. Although childbirth is a leading reason for hospital admission in the United States, obstetric data systems both within and across hospitals "remain rudimentary and lack standardization."[28] It is interesting that even in areas with more robust literature, such as maternal and infant health outcomes, the development of standard terminology is a recognized deficiency that has yet to be addressed. The move from paper charts to the increasingly widespread use of electronic medical records provides a valuable opportunity to

document and collect standardized data on maternal and infant outcomes as well as nonmedical and process outcomes both within and across hospitals. The collection of validated outcome measures across time and hospitals would facilitate the development of best practices that can be replicated in a variety of settings. However, the current lack of standardized outcome measures impedes utilizing the full power of this technology and needs to be addressed.

Finally, our research methodology has some limitations that deserve discussion. First, although the phase 2 Delphi questionnaire included a range of issues beyond health systems, the focus on questions about contextual and health systems factors during the semistructured interviews in phase 1 could have primed the respondents to rank these items higher during the phase 2 prioritization. Second, the small sample size of our stakeholder panel limited the ability to examine differences in priorities across stakeholder groups as well as the generalizability of our findings. Finally, because of the small overall sample size, attempts to include a spectrum of clinical maternity care (e.g. physicians, midwives, and nurse practitioners) resulted in the clinician group being larger than the other stakeholder groups.

Conclusions

The top 10 future research needs as prioritized by stakeholders fall into three overarching categories: health systems and contextual issues (category A), standardized measurement and collection of data on short- and long-term maternal and infant outcomes (category B), and understanding how patients perceive risk and how best to communicate risk of mode of delivery after prior cesarean (category C). Within category A, stakeholders felt it was important to study institutional and systems level barriers and facilitators to providing and delivering safe trials of labor after cesarean, including how the "immediately available" requirement is understood and implemented, and concerns about legal liability. Within category B, stakeholders prioritized standardized measurement and collection of data on short- and long-term maternal and infant clinical and psychosocial outcomes, and emphasized the importance of agreement on clear and precise definitions and methods of ascertainment both within and across hospitals. With regard to category C, stakeholders prioritized research on how patients perceive the risks of trial of labor (TOL) compared with repeat cesarean delivery, how best to frame and communicate the risks of each option, and the most effective way to present information so that women can make an informed choice that incorporates their preferences.

References

1. Hamilton BE Martin JA, Ventura SJ. Births: Preliminary data for 2010. Natl Vital Stat Rep. 2011;60(2). www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr Aaccessed January 9, 2012.

2. Martin JA, Hamilton BE, Sutton PD, et al. Births: Final data for 2007. Natl Vital Stat Rep. 2010;58(24). www.cdc.gov/nchs/products/nvsr.htm

3. National Institutes of Health Consensus Development Conference Statement. Vaginal Birth After Cesarean: New Insights, March 8-10, 2010. Obstet Gynecol. 2010 Jun;115 (6):1279-95. PMID: 20502301.

4. McMahon M, Luther E, Bowes W, et al. Comparison of a trial of labor with an elective second cesarean section. N Engl J Med. 1996;335(10):689-95. PMID: 8703167.

5. Guise JM, Eden K, Emeis C, et al. Vaginal birth after cesarean: new insights. Evid Rep Technol Assess (Full Rep). 2010 Mar(191):1-397. PMID: 20629481.

6. Caron A, Neuhauser D. The effect of public accountability on hospital performance: trends in rates for cesarean sections and vaginal births after cesarean section in Cleveland, Ohio. Qual Manag Health Care. 1999;7(2):1-10. PMID: 10346457.

7. Macones GA. Clinical outcomes in VBAC attempts: what to say to patients? Am J Obstet Gynecol. 2008 Jul;199(1):1-2. PMID: 18585519.

8. Sinha IP, Smyth RL, Williamson PR. Using the Delphi technique to determine which outcomes to measure in clinical trials: recommendations for the future based on a systematic review of existing studies. PLoS Med. 2011;8(1):e1000393. PMID: 21283604.

9. Korst LM, Gregory KD, Fridman M, et al. Nonclinical factors affecting women's access to trial of labor after cesarean delivery. Clin Perinatol. 2011 Jun;38(2):193-216. PMID: 21645789.

10. ACOG Practice bulletin no. 115: Vaginal birth after previous cesarean delivery. Obstet Gynecol. 2010 Aug;116(2 pt 1):450-63.

11. Signore C, Spong CY. Vaginal birth after cesarean: new insights manuscripts from an NIH Consensus Development Conference, March 8-10, 2010. Semin Perinatol. 2010 Oct;34(5):309-10. PMID: 20869544.

12. Maastrict University Medical Center. Current Dutch practice on caesarean sections: Identification of barriers and facilitators for optimal care (SIMPLE). Bethesda (MD): National Library of Medicine (U.S.) [accessed August 23, 2011]: Available from: clinicaltrials.gov/ct2/show/NCT01261676.

13. Roth L. Legal and insurance environments impact and health practices (abstract). University of Arizona, Award Number 0958190. 2010 June 2.

14. Chinese University of Hong Kong. Vaginal birth after caesarean section - effect on maternal psychosocial function. Bethesda (MD): National Library of Medicine. clinicaltrials.gov/ct2/show/NCT00294411. Accessed August 23, 2011.

15. University of British Columbia. Impact of doula support on childbirth outcomes for women undergoing a vaginal birth after cesarean (VBAC). Bethesda (MD): National Library of Medicine. clinicaltrials.gov/ct2/show/NCT01216098. Accessed August 23, 2011.

16. Taipei Medical University WanFang Hospital. Exploring Taiwanese womens' decision-making regarding vaginal birth after caesarean section. Bethesda (MD): National Library of Medicine. clinicaltrials.gov/ct2/show/NCT01210300. Accessed August 23, 2011.

17. Leeman LM, King VJ. Increasing patient access to VBAC: New NIH and ACOG recommendations. Am Fam Physician. 2011;83(2):121-7. PMID: 21243986.

18. Scott JR. Solving the vaginal birth after cesarean dilemma. Obstet Gynecol. 2010;115(6):1112-3. PMID: 20502277.

19. Go MD, Emeis C, Guise JM, et al. Fetal and neonatal morbidity and mortality following delivery after previous cesarean. Clin Perinatol. 2011;38(2):311-9. PMID: 21645798.

20. Bonanno C, Clausing M, Berkowitz R. VBAC: a medicolegal perspective. Clin Perinatol. 2011;38(2):217-25. PMID: 21645790.

21. Cheng YW, Eden KB, Marshall N, et al. Delivery after prior cesarean: maternal morbidity and mortality. Clin Perinatol. 2011;38(2):297-309. PMID: 21645797.

22. Keirse MJ. Home birth: gone away, gone astray, and here to stay. Birth. 2010;37(4):341-6. PMID: 21083728.

23. King TL. Can a vaginal birth after cesarean delivery be a normal labor and birth? Lessons from midwifery applied to trial of labor after a previous cesarean delivery. Clin Perinatol. 2011;38(2):247-63. PMID: 21645793.

24. Grivell RM, Dodd JM. Short- and long-term outcomes after cesarean section. Expert Review of Obstetrics and Gynecology. 2011;6(2):205-15.

25. Grivell RM, Barreto MP, Dodd JM. The influence of intrapartum factors on risk of uterine rupture and successful vaginal birth after cesarean delivery. Clin Perinatol. 2011;38(2):265-75. PMID: 21645794.

26. Oregon Health & Science University. Measuring preferences for childbirth after cesarean. Bethesda (MD): National Library of Medicine (U.S.) [accessed August 23, 2011]: Available from: clinicaltrials.gov/ct2/show/NCT00267735.

27. Chervenak FA, McCullough LB. An ethical framework for the informed consent process for trial of labor after cesarean delivery. Clin Perinatol. 2011;38(2):227-31. PMID: 21645791.

28. MacDorman M, Declercq E, Menacker F. Recent trends and patterns in cesarean and vaginal birth after cesarean (VBAC) deliveries in the United States. Clin Perinatol. 2011;38(2):179-92. PMID: 21645788.

Abbreviations

ACOG	American Congress of Obstetricians and Gynecologists
AHRQ	Agency for Healthcare Research and Quality
EHC	Effective Health Care
EPC	Evidence-based Practice Center
ERCD	Elective repeat cesarean delivery
FTP	Failure to progress
ICAN	International Cesarean Awareness Network
NICHD	National Institutes of Child Health & Human Development
TOL	Trial of labor
VBAC	Vaginal birth after cesarean

Appendix A. Stakeholder Invitation 1

Sample Stakeholder Invitation Letter
Dear [Stakeholder],
The Oregon Evidence-based Practice Center (EPC) was commissioned by the Agency for Healthcare Research and Quality (AHRQ) to develop a national research agenda in the area of Vaginal Birth after Cesarean (VBAC). We are particularly interested in identifying topics stakeholders struggle with in clinical decisionmaking and health policy. **You have been nominated as a stakeholder with an interest in this area and we would like to invite you to participate in this forum.**

This project builds on the Oregon EPC's 2010 evidence report on Vaginal Birth after Cesarean, which provided the evidence base for the NIH consensus conference on VBAC. Although the 2010 report identified pertinent research gaps related to clinical outcomes for mother and infant, we know little about the contextual and health care delivery system factors that influence decisionmaking about VBAC and repeat cesarean. In phase 1 of the project, we will conduct a series of interviews with key stakeholders - including medical liability and insurance company representatives, hospital administrators, consumer advocates, clinicians, patients and others – in order to brainstorm the range of nonmedical factors that might be influencing policy and practice on VBAC. **Your involvement would include participation in a 30-45 minute telephone interview, at a time that is convenient for you, in May 2011.**

In phase 2 of the project we will assemble a panel of 9-10 stakeholders to prioritize the range of identified future research needs – including both the health care delivery system research needs identified in phase 1 and the maternal and infant health outcome research needs identified in the 2010 evidence report. **Stakeholders will be asked to complete 1-3 rounds of a web-based survey to prioritize the list of future research needs, in June 2011.**

I sincerely hope you will be able to participate in this important work. The results of this project will be invaluable to setting the research agenda, and ultimately to improving policy and practice, in the area of VBAC. **We are hoping to set up interviews quickly, so would appreciate confirmation of participation by May 10th.**

If you have any questions, or would like additional information, please feel free to contact me at cottrele@ohsu.edu.

Sincerely,

Erika Cottrell, PhD, MPP
Principal Investigator
Oregon Evidence-based Practice Center
Oregon Health & Science University

Appendix B. Stakeholder Invitation 2

Sample Stakeholder Invitation Letter

Dear [Stakeholder],

The Oregon Evidence-based Practice Center (EPC) was commissioned by the Agency for Healthcare Research and Quality (AHRQ) to develop a national research agenda in the area of Vaginal Birth after Cesarean (VBAC). We are particularly interested in identifying topics stakeholders struggle with in clinical decisionmaking and health policy. **You have been nominated as a stakeholder with an interest in this area and we would like to invite you to participate in this forum.**

This project builds on the Oregon EPC's 2010 evidence report on Vaginal Birth after Cesarean, which provided the evidence base for the NIH consensus conference on VBAC. Although the 2010 report identified pertinent research gaps related to clinical outcomes for mother and infant, we know little about the contextual and health care delivery system factors that influence decisionmaking about VBAC and repeat cesarean. In phase 1 of the project, we will conduct a series of interviews with key stakeholders - including medical liability and insurance company representatives, hospital administrators, consumer advocates, clinicians, patients and others – in order to brainstorm the range of nonmedical factors that might be influencing policy and practice on VBAC. **Your involvement would include participation in a 30-45 minute telephone interview, at a time that is convenient for you, in May 2011.**

In phase 2 of the project we will assemble a panel of 9-10 stakeholders to prioritize the range of identified future research needs – including both the health care delivery system research needs identified in phase 1 and the maternal and infant health outcome research needs identified in the 2010 evidence report. **Stakeholders will be asked to complete 1-3 rounds of a web-based survey to prioritize the list of future research needs, in June 2011.**

I sincerely hope you will be able to participate in this important work. The results of this project will be invaluable to setting the research agenda, and ultimately to improving policy and practice, in the area of VBAC. **We are hoping to set up interviews quickly, so would appreciate confirmation of participation by May 10th.**

If you have any questions, or would like additional information, please feel free to contact me at cottrele@ohsu.edu.

Sincerely,

Erika Cottrell, PhD, MPP
Principal Investigator
Oregon Evidence-based Practice Center
Oregon Health & Science University

Appendix C. Semistructured Interview Questions (Interview Guide)

The Oregon Evidence-based Practice Center (EPC) was commissioned by the Agency for Healthcare Research and Quality (AHRQ) to develop a national research agenda in the area of Vaginal Birth after Cesarean (VBAC). We are particularly interested in identifying topics stakeholders struggle with in clinical decisionmaking and health policy.

This project builds on the Oregon EPC's 2010 evidence report on Vaginal Birth after Cesarean, which provided the evidence base for the NIH consensus conference on VBAC. Although the 2010 report identified pertinent research gaps related to clinical outcomes for mother and infant, we know little about the contextual and health care delivery system factors that influence decisionmaking about VBAC and repeat cesarean (see attached document for further details). In phase 1 of the project, we will conduct a series of interviews with key stakeholders - including medical liability and insurance company representatives, hospital administrators, consumer advocates, clinicians, patients and others – in order to brainstorm the range of nonmedical factors that might be influencing policy and practice on VBAC.

In phase 2 of the project we will assemble a panel of 9-10 stakeholders to prioritize the range of identified future research needs – including both the health care delivery system research needs identified in phase 1 and the maternal and infant health outcome research needs identified in the 2010 evidence report.

The 2010 report concluded that relatively unexamined contextual and health care delivery systems factors such as medical liability, economics, hospital structure, and staffing may need to be addressed in order to more appropriately prioritize topics for future research. In particular, we are looking for gaps in our knowledge related in the following areas:

1. Rates and patterns of utilization of trial of labor after prior cesarean, vaginal birth after cesarean, and repeat cesarean delivery in the United States?
2. Nonmedical factors (e.g. provider type, hospital type) that influence the patterns and utilization of trial of labor after prior cesarean?

We are especially interested in investigating what information sources are instrumental in making decisions about VBAC, the key barriers to offering TOLAC and what additional evidence is needed to facilitate the decision making process. Our ultimate goal is to uncover future research needs in the area, especially with regard to the non-medical drivers of policy and practice surrounding TOLAC and VBAC.

QUESTIONS FOR DISCUSSION

Legal/liability/policy/consumer advocate:

1. We are aware that people wear a number of hats….what perspective are you coming from during this interview? Consumer advocate? Patient? Clinician?
2. Can you give us a sense of your/your organization's perspective on TOLAC/VBAC? (official/unofficial policy?)
3. In your mind, what are the barriers to routinely offering TOLAC? (probes: institutional policy, institutional culture, availability of appropriate staff, liability, previous experience, experience of colleagues, patient preferences, preferences of patients family, other)

Institutional/policy factors?

4. Did the NIH consensus conference and new ACOG statement impact policy and practice surrounding VBAC? If yes, can you give me some specific examples? If no, why do you think this is?
5. In your mind, is there anything that would make VBAC an acceptable/preferred option in any hospital? ("game-changing" evidence, consideration of risk in future pregnancies, framing of evidence, new evidence)

Individual-level factors

6. What information sources do you think are most important in shaping womens' views on VBAC? (media, medical literature, colleagues, friends/family)
7. Does consideration of risks in future pregnancies come into the decision-making process?
8. Is there any information you can think of that would make the decision-making process easier (i.e. that would make you say you would definitely have a VBAC….or alternatively that you would definitely not)?
9. Is there anything that, in your mind, would make VBAC an acceptable/preferred option for any woman (assuming she didn't have other risk factors that necessitated a cesarean delivery)?
10. Of the factors we touched on today, what do you think is the most important in influencing policy and practice related to TOLAC and VBAC?

Providers:

1. What is your role in the hospital? Do you wear more than one hat? How long have you been in practice?
2. Do you do VBAC? (official or unofficial policy on VBAC)
3. How do you usually address VBAC in your practice? Timing of Discussions?
4. Do you have a specific VBAC consent? What about repeat section? Does consent address risks of repeat section for future pregnancies
5. How do you counsel women regarding TOLAC? How do you explain the risks and benefits to her and the baby? Do you discuss risk in future pregnancies (i.e. of repeat cesarean)?
6. Patience preferences? Why do women want a c-section? Do you or other providers push back? After doing first c-section, do you tak about VBAC? What about your partners?
7. Can you give me some specific examples of the barriers to offering TOLAC? (probes: institutional policy, institutional culture, availability of appropriate staff, liability, previous experience, experience of colleagues, patient preferences, preferences of patients family, other).

8. Did the NIH consensus conference and new ACOG statement impact policy and practice surrounding VBAC? If yes, can you give me some specific examples? If no, why do you think this is?
    a. (if don't offer VBAC) In order to support/offer VBAC, what would you need to know?
9. Is there anything about VBAC that you would like to know but haven't been able to find the answer to? If you had better evidence on VBAC what would it be?
10. Is there anything that, in your mind, would make VBAC an acceptable/preferred option in any hospital (assuming no other risk factors that necessitated a cesarean delivery)?
11. Of the factors we touched on today, what do you think is the most important in influencing policy and practice related to TOLAC and VBAC?

Patients:

1. Have you had a VBAC? Can you walk me through your decision-making process?
2. What are your perceptions of VBAC? What is your understanding of the risks and benefits of VBAC for both the mother and baby? What about risks of repeat cesarean?
3. What information sources are most important in shaping your views about VBAC? (friends, family, media, medical literature, Healthcare staff?, etc.)
4. When thinking about your own decision to have/not have a VBAC, what pieces of information are/were most important to you?
5. When thinking about your own decision to have/not have a VBAC, whose opinion do you most value?
6. Is there anything about VBAC that you would like to know but haven't been able to find the answer to?
7. Is there any information you can think of that would make the decision-making process easier (i.e. that would make you say you would definitely have a VBAC….or alternatively that you would definitely not)?
8. Is there anything that, in your mind, would make VBAC an acceptable/preferred option for any woman (assuming she didn't have other risk factors that necessitated a cesarean delivery)?
9. Of the factors we touched on today, what do you think is the most important in shaping your views and decision-making regarding TOLAC and VBAC?

For reference:
ACOG 2010 Practice Bulletin

a. *Because of the risks associated with TOLAC and that uterine rupture and other complications may be unpredictable, the College recommends that TOLAC be* ***undertaken in facilities with staff immediately available*** *to provide emergency care.*
b. *Respect for patient autonomy supports that patients* ***should be allowed to accept increased levels of risk****, however, patients should be clearly informed of such potential increase in risk and management alternatives.*
c. *The decision to offer and pursue TOLAC in a setting in which the option of immediate cesarean delivery is more limited should be carefully considered by patients and their health care providers. In such situations the best alternative may be to* ***refer patients to a facility with available resources****.*

Appendix D. Web-Based Questionnaire 1

Thank you for your participation in the Oregon Evidence-based Practice Center project to prioritize important, feasible research studies that will close evidence gaps identified from the 2010 EPC evidence review entitled "Vaginal Birth after Cesarean Section."

Below is the link to the web based prioritization tool. You can access the prioritization survey by copying the link into your browser.

Link:http://www.surveymonkey.com/s/RK9WDZ9

The prioritization survey will be available from Wednesday, July 6th to Wednesday, July 13th and should take approximately 30-40 minutes to complete. This is the first phase of the prioritization to identify topics and the most lengthy. Once we have identified the top ten priorities, we will follow up with one to two very brief surveys in order to rank the topics.

We realize that this is a busy time of year for all of you, and we are grateful for your time and input. If you are unable to complete the first survey by Monday, July 11th please let us know and we will try to accommodate your schedule.

Please contact Ngoc Wasson at wassonn@ohsu.edu or 503-494-3267, Erika Cottrell at cottrele@ohsu.edu or 503-494-9042, or myself at guisej@ohsu.edu if you have questions.

Thank you again,

Jeanne-Marie Guise, MD, MPH
Principal Investigator
Oregon Evidence-based Practice Center

Erika Cottrell, PhD, MPP
Co-Investigator
Oregon Health & Science University

Ngoc Wasson, MPH
Research Associate
Oregon Evidence-based Practice Center
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Jesse Wagner, BS
Research Assistant
Research Assistant
Oregon Health & Science University

Developing and Prioritizing a Future Research Agenda for VBAC
Section I: Background
We recognize that many of you serve multiple roles and have varying perspectives. What is the primary perspective that you will take in responding to these questions?
Name/Organization Perspective
Clinician
Consumer Advocate
Researcher
Funder of Research

Section IIA: Health Systems Factors
1. Research on barriers to providing safe TOL, including factors that limit the ability of hospitals to meet the "immediately available" requirement (i.e. availability of anesthesiologists, availability of obstetric providers, other resources)
2. Studies to test clinical, institutional, or policy interventions to increase access to safe TOL
Question 2 Priority Response Stats: High- 7 (63.6%), Medium- 2 (18.2%), Low- 2 (18.2%)

3. Development of best practice models based on institutions that are currently offering safe TOL

4. Studies to test the effectiveness of simulation training in increasing capacity to offer safe TOL

5. Clinical and policy relevant studies to address the threat of legal liability on practice patterns regarding TOL vs. elective repeat cesarean delivery (ERCD)

6. Studies of the influence of Medicaid policy and private insurance reimbursement on availability of TOL after cesarean vs. ERCD

7. Studies that correlate benefits and harms of VBAC and ERCD with short and long term health system costs

8. Research on the threshold/tipping point for a change in health policy in response to harms vs. benefits

9. Studies on influence of VBAC policies on trends in home births

Section IIB: Risk, Attitudes, and Decision-making
1. Research on how PATIENTS understand risk, how they respond to different ways of framing risk, and how best to communicate risks of TOL vs. ERCD

2. Research on how PROVIDERS understand risk, how they respond to different ways of framing risk, and how best to communicate risks of TOL vs. ERCD

3. Research on how HEALTH SYSTEM ADMINISTRATORS & LIABILITY COMPANIES understand risk, how they respond to different ways of framing risk, and how best to communicate risks of TOL vs. ERCD

4. Studies of the factors shaping PATIENT attitudes and decision-making on TOL after cesarean

5. Studies of the factors shaping PROVIDER attitudes and decision-making on TOL after cesarean

6. Studies of the factors shaping HEALTH SYSTEM ADMINISTRATOR & LIABILITY COMPANY attitudes and decision-making on TOL after cesarean

7. Research on the relationship between fear of childbirth and decision-making surrounding mode of delivery

Section IIC: Shared decision-making and informed consent

1. Studies to understand whether and how patients and providers work together to make a shared decision about TOL vs. ERCD

2. Studies comparing the efficacy of different types of decision aids for TOL vs. ERCD

3. Studies on the timing of decision aids or other information about the risks and benefits of TOL vs. ERCD (i.e. after the woman's first cesarean vs. waiting until her next pregnancy)

4. Studies of how women are consented for both TOL after previous cesarean and ERCD and whether consent encompasses risks to current and future pregnancies

5. Studies to refine, validate, and implement informed consent templates that are informative, reliable and able to be well documented

Section IID: Maternal and Infant Outcomes

1. Development of standardized measures for short and long-term maternal and infant outcomes

2. Population-level research on patterns of utilization and maternal/infant outcomes of VBAC, TOL with emergent cesarean and ERCD, stratified by race/ethnicity and socioeconomic status

3. Development/utilization of a reliable model or tool to predict the probability of successful VBAC for individual women

4. Development of registries to track frequency and safety of home births, including TOL after cesarean

5. Comparative studies of TYPE OF PROVIDER (OB/GYN, midwife, family practice physician) on patterns of utilization and maternal/infant outcomes of TOL vs. ERCD

6. Comparative studies of DELIVERY SETTING (tertiary care center, community hospital, free standing birth center, at home) on patterns of utilization and outcome of TOL vs. ERCD

7. Investigation of whether antepartum or intrapartum management strategies – such as labor induction – influence rate of TOL vs. ERCD and maternal/infant outcomes

8. Studies comparing outcomes for mother and infant in settings where physicians are "immediately available" vs. settings where physicians are "readily available"

9. Comparison of risk of maternal or infant adverse outcomes during childbirth in general vs. TOL or ERCD

10. Studies to compare impact of TOL vs. ERCD on breastfeeding initiation and continuation

11. Studies to compare impact of TOL vs. ERCD on psychosocial outcomes such as maternal-infant bonding and post-partum depression

12. Surveillance to determine long term maternal and infant clinical outcomes of TOL vs. ERCD

Section III: Recap

1. Please describe any research you are involved in or know of that is related to this project

2. Are there any research priorities that you think are important that were not included in this survey?

3. Additional suggestions/comments?

Section IV: Future Research Needs Communication (Optional)

1. What information would you want this document to include?

2. How would you use this document?

3. How would you like to receive this information? (chapter in evidence report, magazine article, stand alone document, webinar, podcast, journal article, other)

4. Would you like a copy of the final report?

Appendix E. Web-Based Questionnaire 2

Oregon Evidence-based Practice Center Vaginal Birth After Cesarean
Future Research Needs Project

Stakeholder Selected Areas for Top Ten Prioritization (Phase II ranking)

Thank you for your continued participation in our project to develop and prioritize a future research agenda for VBAC. Your input is invaluable to our goal of identifying clinically and policy relevant topics that resonate with key stakeholders.

The purpose of round 2 is to reach consensus on the top 10 future research priorities. A list of the 15 highest ranked topics from round 1 is included below. Please reflect on which topics you feel are the highest priority and rank them from 1-10, with 1 being the most important. There are currently 15 topics listed, so the bottom 5 will not be ranked. When making your prioritization, keep in mind that we are trying to understand what areas of research have the highest potential to make an immediate impact as well as which research topics you feel ought to be conducted first.

Topics For Prioritization	(Please type a number from 1-10)
Factors that limit ability to provide safe TOL and/or meet "immediately available" requirement	Rank: _____
Providers: understanding, framing, communicating risk of TOL vs. ERCD	Rank: _____
Clinical, institutional, or policy interventions to increase access to safe TOL	Rank: _____
Patients: understanding, framing, communicating risk of TOL vs. ERCD	Rank: _____
Providers: factors shaping attitudes/decision-making	Rank: _____
Administrator/liability: understanding, framing, communicating risk of TOL vs. ERCD	Rank: _____
Development/utilization of model/tool to predict probability of successful VBAC	Rank: _____
Comparison of outcomes with "immediately available" vs. "readily available" providers	Rank: _____
Development of best practice models	Rank: _____
Threat of legal liability on practice patterns	Rank: _____
Administrator/liability: factors shaping attitudes/decision-making	Rank: _____
How patients are consented for TOL after previous cesarean and ERCD/discussion of risk in future pregnancies	Rank: _____
Informed consent templates that are informative, reliable and able to be well documented	Rank: _____
Standardized measures for short and long-term maternal and infant outcomes	Rank: _____
Surveillance to determine long term clinical outcomes of TOL vs. ERCD	Rank: _____

Appendix F. Search Strategy for Ongoing Studies

Vaginal Birth After Cesarean: Future Research Needs

Databases and Search Strategies

Name	Date Searched	Platform Provider
Citation Search		
Scopus	08/10/2011	Elsevier
Medline	08/10/2011	OvidSP
Google Scholar	08/10/2011	Google
Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Cochrane Database of Reviews of Effects (DARE)	08/10/2011	Cochrane
Grey Literature Databases		
AHRQ Gold	08/25/2011	http://gold.ahrq.gov/projectsearch/
Foundation Directory Online	08/31/2011	Foundation Center
US National Science Foundation Award Search	08/26/2011	http://www.nsf.gov/awardsearch/
US NIH Clinicaltrials.gov	08/29/2011	http://www.clinicaltrials.gov/
US NIH Reporter	08/25/2011	http://projectreporter.nih.gov/reporter.cfm
US NLM Health Services Research in Progress (HSRProj)	08/26/2011	http://wwwcf.nlm.nih.gov/hsr_project/home_proj.cfm
WHO International Clinical Trials Registry Platform	08/23/2011	http://apps.who.int/trialsearch/AdvSearch.aspx
Individual Websites		
American Pregnancy Association	08/25/2011	http://americanpregnancy.org/
Annals of Internal Medicine	08/10/2011	http://www.annals.org/
Wellcome Trust	08/25/2011	http://www.wellcome.ac.uk/

ClinicalTrials.gov
Search Results 08/23/2011

Advanced search:
SEARCH TERMS: vaginal OR VBAC OR Dystocia OR augmentation OR membranes
RECRUITMENT: Open Studies
STUDY RESULTS: All Studies
CONDITIONS: (cesarean OR caesarean OR delivery OR outcomes OR birth OR childbirth OR induced OR parturition OR labor OR labour) NOT (preterm OR postpartum)
FIRST RECEIVED: from 01/01/2010 to 08/30/2011
RESULTS = 68

ICTRP Website
Search Results 08/23/2011

Search:
TITLE = labor OR labour OR delivery
CONDITION = labor OR labour OR delivery OR preterm OR term
DATE OF REGISTRATION = 01/01/2010 to 24/08/2011
RESULTS = 64